IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF TEXAS
MARSHALL DIVISION

HEARTFLOW, INC.,

Plaintiff,

v.

CLEERLY, INC.

Defendant.

Civil Action No. 2:26-cv-292

COMPLAINT AND DEMAND FOR JURY TRIAL

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiff Heartflow, Inc. ("Heartflow" or "Plaintiff"), by and through its undersigned counsel, files this complaint under 35 U.S.C. § 271 for Patent Infringement against Defendant Cleerly, Inc. ("Cleerly") ("Defendant") and further alleges as follows, upon actual knowledge with respect to itself and its own acts, and upon information and belief as to all other matters.

OVERVIEW

1. This is an action for patent infringement by Heartflow, arising from one of the most egregious examples of piracy in the medical technology industry. Defendant Cleerly was founded by Dr. James K. Min, who served as a trusted consultant to Heartflow from 2012 to 2017 during the company's most formative years, and who incorporated Cleerly while still under contract with Heartflow and bound by confidentiality, non-compete, and invention assignment obligations.

2. After gaining intimate access to Heartflow's revolutionary cardiovascular diagnostic technology, trade secrets, and confidential business information—and while still bound by his contractual obligations to Heartflow—Dr. Min, without informing his colleagues at Heartflow, incorporated Cleerly and launched a competing enterprise built upon Heartflow's pioneering innovations.

3. In or around June 2017, Dr. Min was seeking funding for Cleerly while explaining that Cleerly's focus is to use machine learning on medical images to derive quantitative measures, which was in the same field as his work at Heartflow.

4. By this action, Heartflow seeks to protect the extraordinary investment—measured in hundreds of millions of dollars, decades of research protected by hundreds of patents, and the contributions of countless scientists, engineers, and physicians—that created the world's first AI-powered, non-invasive cardiac diagnostic platform, as recognized by the U.S. Food and Drug Administration (FDA) and Centers for Medicare & Medicaid Services (CMS).

5. In particular, recognizing the novelty in Heartflow's pioneering AI-powered, non-invasive cardiac diagnostic platform—that is protected by over 600 patents including the patents asserted in this complaint—the FDA granted Heartflow de novo clearance on November 26, 2014. Ex. 1 (https://www.accessdata.fda.gov/cdrh_docs/reviews/DEN130045.pdf). The de novo classification provides a pathway to classify "novel" medical devices for which there is no marketed "predicate device." Ex. 2 (https://www.fda.gov/medical-devices/premarket-submissions-selecting-and-preparing-correct-submission/de-novo-classification-request#What_is_a_De_Novo_Classification_Request).

6. On November 6, 2017, the CMS assigned a "New Technology" Ambulatory Payment Classification recognizing Heartflow's first-of-its-kind, non-invasive technology that helps clinicians diagnose and treat patients with suspected coronary artery disease (CAD). (https://ir.heartflow.com/news-releases/news-release-details/heartflow-announces-decision-centers-medicare-medicaid-services).

THE PARTIES

7. Plaintiff Heartflow, Inc. is a Delaware corporation with its principal place of business at 331 E. Evelyn Avenue, Mountain View, California 94041.

8. Upon information and belief, Defendant Cleerly, Inc. is a Delaware corporation incorporated on July 19, 2016, with its principal place of business at 1099 18th Street, Suite 2860, Denver, CO, 80202. Cleerly was incorporated by Dr. James K. Min, who listed himself as President and CEO at the time of incorporation. Ex. 3 (Cleerly Incorporation Information, https://www.sec.gov/Archives/edgar/data/1714014/000171401417000001/xslFormDX01/primary_doc.xml).

HEARTFLOW

A. The Founders' Vision: From Stanford to a Revolution in Cardiac Care

9. Heartflow's story began not in a boardroom, but in a hospital bed. In 1978, a fifteen-year-old boy named Charles Taylor lay near death from a ruptured appendix. https://www.nobhillgazette.com/wellness/bay-area-based-Heartflow-is-using-3d-modeling-to-produce-a-better-noninvasive-test-for/article_221da804-d9e7-5cf3-8deb-488e84c2bfe2.html. After intense weeks in the hospital, young Taylor recovered—and was so inspired by the surgeon who saved his life that he resolved to pursue a career in science and medicine. *Id.* That journey would ultimately lead Dr. Charles Taylor to revolutionize how heart disease—the number one killer of men and women worldwide—is diagnosed and treated. *Id.*

10. By 1993, Dr. Taylor was a Ph.D. student in engineering at Stanford University. *Id.* That year, he attended a lecture that would change his life. *Id.* Dr. Christopher Zarins, Stanford's new chief of vascular surgery, gave a talk titled, "Blood Flow and Your Health." *Id.* "This is my calling," Dr. Taylor thought, as he listened to Dr. Zarins's lecture. *Id.* The next day, he went to see Dr. Zarins and asked, "Is there a role for me to work on this with you?" *Id.* That question would launch a decades-long partnership that would ultimately transform cardiovascular medicine. Dr. Zarins became Dr. Taylor's Ph.D. co-supervisor, and Dr. Taylor's doctoral thesis focused on using computers to simulate blood flow in arteries, building on Dr. Zarins's research on understanding

atherosclerosis including blood flow and plaque. *Id.* "One of [Dr. Taylor's] big ideas . . . was to use computer images to create a patient-specific model." *Id.* As leading experts, they published hundreds of articles and book chapters on their research related to atherosclerosis, plaque, blood flow, and medical image analysis.

11. Leveraging their foundational research, Dr. Taylor and Dr. Zarins cofounded Cardiovascular Simulation, Inc. in 2007. *Id.* The company became the first company-in-residence at the Mountain View-based Fogarty Institute for Innovation, a medical technology incubator. *Id.* In 2010, the company was renamed Heartflow, Inc. *Id.*

B. Heartflow Brings Dr. Min Into Its Inner Circle

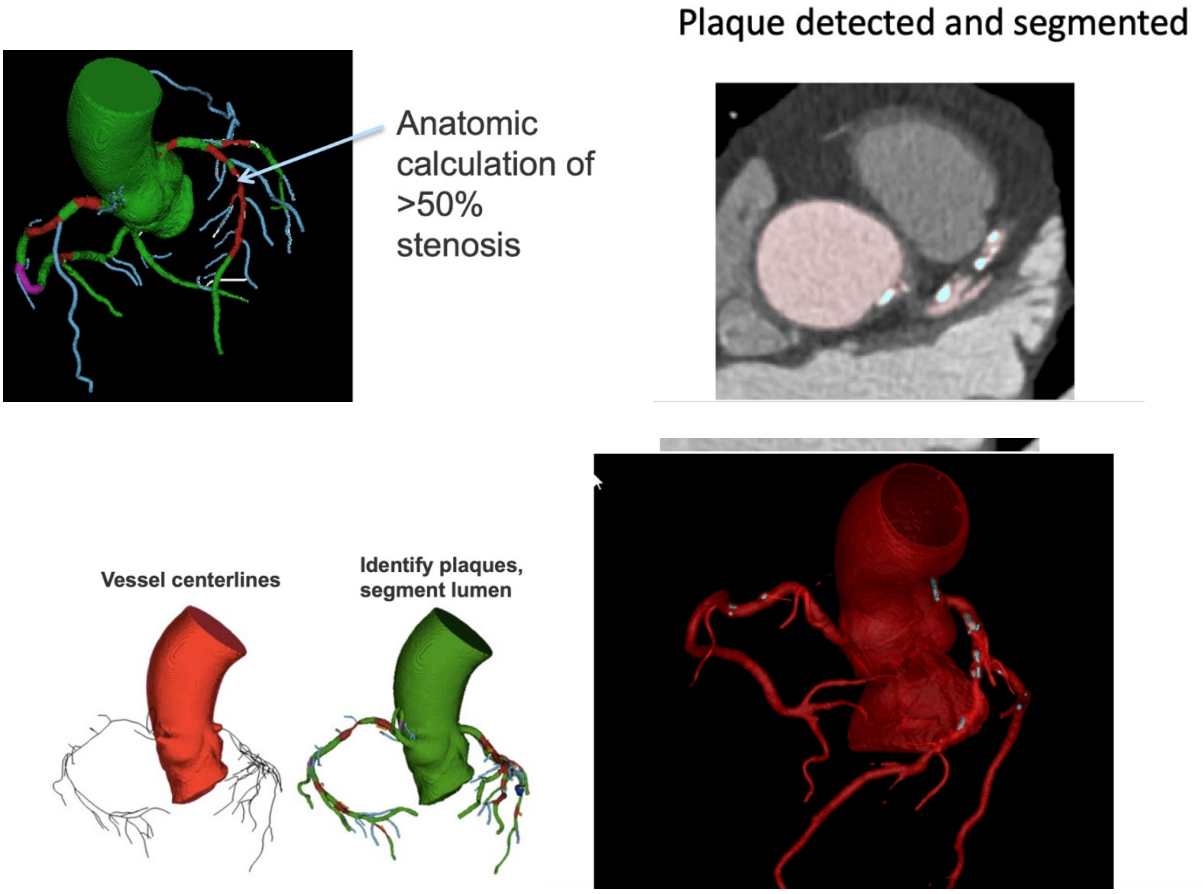
12. When Heartflow's founders, Dr. Zarins, Dr. Taylor, and CEO John Stevens, set out to develop their revolutionary cardiac imaging technology, they hired Dr. James Min, a cardiologist at Weill Cornell Medical College with a focus on cardiac CT imaging.

13. Heartflow's leadership approached Dr. Min, and extensive discussions followed. Those conversations led to an agreement: Dr. Min would serve as the principal investigator for Heartflow's landmark DeFACTO clinical trial (Determination of Fractional Flow Reserve by Anatomic Computed Tomographic Angiography), which launched in 2010 and culminated in a high-profile publication in the *Journal of the American Medical Association* two years later. Ex. 4 (Min, James K., et al. "Diagnostic Accuracy of Fractional Flow Reserve from Anatomic CT Angiography," 308 JAMA 12, 1237 (Sep. 26, 2012)).

14. At a nascent stage of the collaboration, Heartflow took steps to protect its proprietary information. On June 16, 2010, Dr. Min signed a Non-Disclosure Agreement with Cardiovascular Simulation, Inc. that transferred over to Heartflow. Ex. 5 (Min Agreements). Under that agreement, Dr. Min committed to safeguarding all of Heartflow's confidential technical and business information. *Id.* He pledged to use that information solely for purposes related to his work

with Heartflow. *Id.* He acknowledged that these confidentiality duties would persist until the protected information entered the public domain. *Id.* And he recognized that any violation thereof would inflict irreparable injury on Heartflow. *Id.* On December 5, 2012, Dr. Min agreed to assign to Heartflow all right, title, and interest in and to any invention, improvement, discovery, process, formula, technique, method, trade secret, or other intellectual property, made, conceived, developed, or first reduced to practice by him in connection with his performance of the Services and applicable to the Field. Ex. 5. The agreement was not a promise to assign. By signing the agreement, Dr. Min acknowledged that he "hereby assigns to the [Heartflow] all right, title, and interest in and to any such Inventions, irrespective of whether such Inventions are disclosed." *Id.* Thus, Dr. Min's inventions were assigned to Heartflow based on his agreement.

15. Assured by these protections, Heartflow opened its doors to Dr. Min. The company's executives and engineers treated him as a trusted insider. They shared their strategic vision; their proprietary algorithms; their analysis workflow; behind-the-scenes demonstrations of how Heartflow modeled anatomy, plaque, and blood flow from CT images; their product roadmaps; clinical data; and their most closely guarded technical secrets. Dr. Min became a fixture in Heartflow's inner circle. One example of behind the scenes confidential Heartflow information is shown below, including methods, algorithms, and visuals for how Heartflow detected and quantified both coronary anatomy and plaque from CT images to create their first product, FFRct, and other novel R&D dating back to its early days while Dr. Min was working with Heartflow.



16. In demonstration of being exposed to key methods, Dr. Min co-authored a paper in 2013 with Heartflow authors on the techniques behind the Heartflow analysis, which required

intimate knowledge of the technology and process. The paper specifically states: "This segmentation process involves extracting the topology of the coronary artery tree; identifying, analyzing, and segmenting coronary plaques in each vessel; and extracting the luminal boundary." Heartflow has since commercialized FDA-cleared stenosis and plaque quantification products built on this original vision and inventions established early in the company's innovative history. Many detailed methods for analyzing CT images, algorithm and human inspection processes, and anatomy and plaque analysis were kept internal to Heartflow and seen only by those with confidential access. Dr. Min had early visibility to Heartflow's proprietary methods and inventions related to not only FFR_{CT}, but also AI analysis of medical images, coronary anatomy and plaque quantification, and software-as-a-service business models that allow CT images to be analyzed by algorithms with human oversight. All of these methods and knowledge formed the basis of what Dr. Min created as Cleerly.

C. Heartflow's Revolutionary Technology

17. Heartflow's FDA-approved technologies form Heartflow's integrated AI diagnostic platform and are protected by hundreds of patents:

- FFR_{CT} Analysis evaluates how artery narrowing (stenosis) affects blood flow to a patient's heart through a personalized three-dimensional model.
- Roadmap Analysis visualizes and quantifies the location and severity of stenoses on CCTA images.
- Plaque Analysis characterizes the composition and volume of plaque within the coronary arteries.
- Navigator combines anatomy, plaque, and physiology information and visuals into a precision tool for planning interventional procedures like coronary stents.

18. Working in concert, Heartflow's platforms leverage AI-powered assessment from a single CCTA scan to identify patients—whether symptomatic or asymptomatic—who may have an elevated risk of heart attack and how to best plan their medical or interventional treatment.

19. Heartflow commercialized its first product, the Fractional Flow Reserve derived from Computed Tomography ("FFRCT") Analysis, in 2014 after de novo clearance from the U.S. Food and Drug Administration ("FDA"). Ex. 6 (FDA Approves Heartflow FFRCT: Non-Invasive Method for Determining Coronary Ischemia, https://www.ptca.org/news/2014/1126_HEARTFLOW.html). This groundbreaking technology offered a noninvasive method to detect and evaluate the severity of coronary artery disease. Using standard coronary CT angiography ("CCTA") images, FFRCT creates a three-dimensional model—a digital twin—of the patient's heart, coronary anatomy, and calculates blood flow to identify pressure differences within the arteries. https://www.nsf.gov/science-matters/Heartflows-ai-powered-medical-technology-debuts-nasdaq. This enables physicians to identify potential blockages that could precipitate a heart attack while also providing a functional assessment of the patient's coronary artery disease, helping them decide the optimal medical, stent, or surgical treatment of each patient. *Id.*

20. Highlighting the significance of de novo FDA approval obtained by Heartflow, Cleerly's founder and CEO—Dr. Min—described the development as "fantastic news," noting that Heartflow was at the helm of "disruptive technology" that "for the first time facilitates a 'one stop shop' for discrimination of individuals who suffer from myocardial ischemia" and "identification of the specific coronary artery lesions that are the cause." Ex. 6 (excerpted below).

Dynamics Applied to Cardiac Computed Tomography for Noninvasive Quantification of Fractional Flow Reserve -- *JACC*

Dr. James K. Min

Commenting on the importance of the FDA approval, Dr. James K. Min, Director of the Dalio Institute of Cardiovascular Imaging at NewYork-Presbyterian Hospital/Weill-Cornell Medical Center, told Angioplasty.Org:

"The FDA approval of the HeartFlow FFR_{CT} technology is fantastic news to patients with suspected coronary artery disease and the physicians caring for these individuals. Based upon several prospective multicenter studies, FFR_{CT} has been proven a disruptive technology that harnesses the power of computational fluid dynamics for diagnosis of physiologically-relevant coronary heart disease. Coupled with the anatomic information provided by coronary CT angiography, FFR_{CT} for the first time facilitates a 'one stop shop' for discrimination of individuals who suffer from myocardial ischemia as well as the identification of the specific coronary artery lesions that are the cause."

21. All along, Heartflow was protecting its pioneering technology by obtaining worldwide patent coverage, including in the field of using machine learning techniques in combination with one or more of FFR_{CT}, Plaque, and coronary disease analysis. In 2016, Heartflow further enhanced its FFR_{CT} technology by incorporating cloud-based infrastructure, enabling faster and more secure data transfer with clinicians, and improved machine learning algorithms. *Id.* Heartflow maintains an ongoing R&D pipeline of continued improvements and innovations, many of which leverage early inventions and patents. Backed by extensive years of R&D and protected by its patents, Heartflow also developed improvements to FFR_{CT} technology, new AI-powered products: Roadmap Analysis, Plaque Analysis, and Navigator. Dr. Min was well-aware of Heartflow's R&D in each of these technologies including Plaque Analysis through his inside knowledge of Heartflow and through the collaboration that was ongoing between Heartflow and MDDX Research and Informatics, a company in which Dr. Min had ownership stake.

D. A World Leader Protected by Intellectual Property

22. Considering the revolutionary nature of its technology, Heartflow diligently sought to protect its groundbreaking research efforts, including through patents, and patent offices around the world have awarded numerous patents to Heartflow. In October 2015, the United States Patent and Trademark Office had issued Heartflow its fiftieth U.S. patent. https://ir.Heartflow.com/news-releases/news-release-details/Heartflow-secures-50th-us-patent. As then-CEO Dr. John H.

Stevens stated at the time: "At our very core, we drive meaningful and continuous innovation. Aggressively protecting our technology is essential to our work." *Id.*

23. Today, Heartflow has been granted over 600 patents globally, spanning 100 unique patent families. Dr. Taylor alone has over 220 issued or pending patents worldwide.

24. These patents include the six patents asserted in this complaint, including U.S. Patent Nos. 11,288,813 (Ex. 7), 11,382,569 (Ex. 8), 9,770,303 (Ex. 9), 9,839,399 (Ex. 10), 9,607,386 (Ex. 11), and 11,013,425 (Ex. 12) (collectively "Asserted Patents").

25. Heartflow's early work within the fields of AI analysis of medical images, coronary anatomy and plaque quantification, and other related features is evidenced by the hundreds of diverse patents granted to Heartflow including, for example, asserted patent No. 9,770,303 that is specifically tied to implementing innovative AI techniques for performing plaque analysis and has a priority date of Dec 18, 2013. There are many other such diverse set of patents in Heartflow's portfolio.

E. Recognition of Technical Innovation, Commercial Success, and Industry Praise of Heartflow's Technology Protected by Heartflow's Patents

26. The de novo approval provided to Heartflow confirms that there was no "predicate device" and that Heartflow's use of FFR_{CT} and 3D coronary anatomy models for the "clinical quantitative and qualitative analysis" of cardiac CT images warranted a classification for a "novel" medical device that is protected by Heartflow patents including the Asserted Patents. Exs. 1-2.

27. The *New England Journal of Medicine* cited Heartflow as being the most utilized AI-based technology in the U.S. based on insurance claims analysis. https://ai.nejm.org/doi/full/10.1056/AIoa2300030.

28. Heartflow paved the way for AI-based technologies to have codes and receive payment by Medicare and now has reimbursement for both FFR_{CT} and Plaque Analysis.

Assignment of the "New Technology" Ambulatory Payment Classification by CMS also confirms that Heartflow's technology and patents are directed to "New Technology." https://ir.heartflow.com/news-releases/news-release-details/heartflow-announces-decision-centers-medicare-medicaid-services. As part of receiving the New Technology Ambulatory Payment Classification by CMS, Heartflow's technology—including the use of machine learning/AI models in combination with FFR_{CT} platforms and 3D models to diagnose coronary artery disease—received industry praise from commenters who remarked that such techniques were not routine or conventional and were a technical improvement over existing solutions:

> Commenters asserted that a FFR_{CT} service provides information that cannot be obtained from standard analysis of a coronary computed tomography angiography image. Several commenters stated that FFR_{CT} services can improve the quality of screening for coronary artery disease (CAD) while reducing costs. That is, the commenters stated that, unlike a coronary computed tomography angiography service, which merely produces images, the FFR_{CT} service is able to directly produce FFR_{CT} values by creating a 3-D model of the patient's coronary arteries using the previously acquired image. Moreover,

https://s3.amazonaws.com/public-inspection.federalregister.gov/2017-23932.pdf (Excerpts) (Ex. 13 at 280).

> Commenters stated that, many times, a coronary computed tomography angiography indicates that a beneficiary may potentially have CAD and that without FFR_{CT}, providers will often request an invasive coronary angiogram to verify the presence of CAD. In many cases, the invasive coronary angiogram finds no occurrence of CAD. FFR_{CT} services can provide analytic services not otherwise available to determine fractional flow rates in coronary arteries using the original coronary computed tomography angiography image and show whether a beneficiary has CAD without performing a coronary procedure.

Id.

29. The CMS noted that Heartflow's FFR_{CT} platform "is a separate and distinct service from the original coronary computed tomography angiography service" and that "the FFR_{CT} service generates data on FFR values that can only be obtained by performing the FFR_{CT} service." *Id.* at 284.

30. Heartflow's FFR_{CT} Analysis, Roadmap Analysis, and Plaque Analysis products are supported by the ACC/AHA Chest Pain Guideline and backed by more than 600 peer-reviewed publications. https://ir.heartflow.com/news-releases/news-release-details/heartflow-closes-98-million-convertible-notes-financing. Heartflow maintains deep partnerships with more than 1,400 hospitals in the U.S. and more globally, including 80% of the top 50 heart hospitals in the U.S. Ex. 14 (Heartflow Achieves Landmark Milestone of 500,000 Patients Assessed for Coronary Artery Disease (CAD) with FFR_{CT} Analysis, https://finance.yahoo.com/news/heartflow-achieves-landmark-milestone-250-140000565.html).

31. Heartflow received significant industry praise for implementing AI techniques, machine learning models, and deep learning models to manage CAD. For example, The Guardian credited Heartflow for leading the charge to rely on AI to create a "revolution" and transform the National Health Services. https://www.theguardian.com/technology/2018/jul/04/its-going-create-revolution-how-ai-transforming-nhs (Ex. 15).

32. Additional examples of industry praise and recognition for Heartflow's patented technology include:

- Award in patient health magazine recognizing non-invasive AI analysis of a patient's heart: https://www.prevention.com/health/g30198374/health-breakthrough-awards/ (Ex. 16)
- 2019 Fast company AI award: https://www.fastcompany.com/most-innovative-companies/2019/sectors/artificial-intelligence (Ex. 17)
- 2011 EuroPCR Innovation Award: https://ir.heartflow.com/news-releases/news-release-details/heartflow-receives-2011-europcr-innovation-award (Ex. 18)
- Diagnosis of Plaque Rupture: https://ir.heartflow.com/news-releases/news-release-details/technology-heartflow-provides-insights-help-identify-coronary (Ex. 19)

33. Further, leading medical device companies such as GE, Siemens, and Philips entered into collaborative agreements with Heartflow recognizing the innovative use of AI and machine learning techniques:

- https://www.reuters.com/article/business/ge-health care-heartflow-enters-into-global-collaboration-agreement-idUSFWN1JX0BA/.
- https://cdn-corpweb.heartflow.com/assets/docs/Siemens-Healthineers_HeartFlow_Collaboration-3-16-17/Siemens-Healthineers_HeartFlow_Collaboration-3-16-17.html.
- https://www.usa.philips.com/a-w/about/news/archive/standard/news/press/2017/20170828-philips-and-heartflow-announce-global-collaboration-agreement.html?srsltid=AfmBOord28KbSucp0oOgNK5p3bFZsiGaS1hxNnFDg90CPuzNnUQuwQhx.

34. Imaging Technology News described Heartflow's platform as being directed to "groundbreaking technology" and "technology [that] provides both anatomical and functional assessment of the coronary arteries, a task no other method has accomplished to date." https://www.itnonline.com/article/clinical-applications-ffr-ct (Ex. 20). They further noted that this "technology can help determine if any of the lesions are severely limiting blood flow and/or which lesion(s) are the most significant." *Id.*

35. On April 5, 2016, Imaging Technology News also described Heartflow's platform as being directed to "Novel technology" that "significantly reduces the need for invasive procedures to diagnose patients suspected of having coronary artery disease" and that it "is the only non-invasive technology to provide physicians insight into both the extent of a patient's arterial blockage and the functional impact the blockage has on blood flow." https://www.itnonline.com/content/one-year-platform-trial-results-reinforce-benefits-ffr-ct (Ex. 21).

36. Cleerly's founder and CEO—Dr. Min—also described Heartflow's technology as "disruptive technology" that "for the first time facilitates a 'one stop shop' for discrimination of individuals who suffer from myocardial ischemia" and "identification of the specific coronary artery lesions that are the cause." Ex. 6.

37. In a video interview discussing Heartflow's technology in or around August 5, 2015, Dr. Min distinguished Heartflow's technology from conventional techniques of detecting coronary artery disease by explaining the technical improvements as below (https://www.dicardiology.com/videos/video-implementation-and-science-behind-ffr-ct):

- "Historically we've had a number of limitations from either functional imaging or from anatomic imaging."
- "From functional imaging we never saw the coronary arteries so that was a huge limitation to it. With coronary CT angiography we found the stenosis but didn't really know whether or not that stenosis was flow limiting and now we do."
- "There's a lot of artifacts that you see with CT perfusion imaging. And again, it doesn't precisely localize the stenosis. Let's say you have an anterior defect in your perfusion and you assume that it's the LAD, the left anterior descending artery. But there might be multiple lesions across the course of that artery and you still are not quite certain which specific lesion causes the ischemia. That's what FFR_{CT} has the benefit of offering."
- "[I]t's a truly disruptive technology . . . [Y]ou're able to pinpoint the exact location at which a patient becomes ischemic."

38. The National Institute for Health and Care Excellence (NICE) in the United Kingdom (UK) also recognized that Heartflow's FFR_{CT} platform "showed high diagnostic accuracy and increased specificity with HeartFlow FFR_{CT}" compared with conventional CCTA alone and that "the committee considered the technology to be **innovative** and understood that its adoption may serve to simplify a complex patient pathway" and solve the problems in the field by reducing the need for invasive measurements and radiation exposure. *See* https://www.nice.org.uk/guidance/htg429/resources/heartflow-ffrct-for-estimating-fractional-flow-reserve-from-coronary-ct-angiography-pdf-1809594120437701 (Ex. 22).

39. Heartflow was recently named one of *Fast Company*'s Most Innovative Companies in Medical Devices for 2025 and won the Innovation in Cardiac Imaging award at the 2025 Global Cardiovascular Awards. https://www.nsf.gov/science-matters/Heartflows-ai-powered-medical-

technology-debuts-nasdaq (Ex. 23). This comes after Heartflow already earned a spot on *Fast Company*'s list of "The World's Most Innovative Companies" only a few years prior. *Id.* Dr. Taylor's "pioneering" work with Heartflow led to his election to the National Academy of Engineering class of 2024. *Id.*

40. Heartflow has raised more than $1.2 billion of capital. *Id.* Thanks to its groundbreaking technology, Heartflow is now recognized as the most widely adopted AI solution in U.S. health care. *Id.* Heartflow's products have been used at over 1,500 hospitals in the United States to diagnose heart disease in over 600,000 patients. *Id.*

41. Heartflow's technology is protected by Heartflow's patents including the Asserted Patents.

CLEERLY, INC.

A. Dr. Min's Secret Formation of Cleerly While Under Contract with Heartflow—From Heartflow's "One Stop Shop" to Cleerly's "All In One platform"

42. On July 19, 2016, while still subject to the Consulting Agreement with Heartflow—including his confidentiality obligations, his non-compete restrictions, and his invention assignment obligations—Dr. Min incorporated Cleerly, Inc. in Delaware without disclosing this to Heartflow. Ex. 3 (Cleerly Incorporation Information, https://www.sec.gov/Archives/edgar/data/1714014/000171401417000001/xslFormDX01/primary_doc.xml). Dr. Min listed himself as President and CEO of Cleerly at the time of incorporation. *Id* (reproduced below).

Name of Issuer
Cleerly, Inc.
Jurisdiction of Incorporation/Organization
DELAWARE
Year of Incorporation/Organization
☐ Over Five Years Ago
☒ Within Last Five Years (Specify Year) 2016
☐ Yet to Be Formed

Issuer	Signature	Name of Signer
Cleerly, Inc.	James K. Min	James K. Min

Title	Date
President & CEO	2017-08-10

Id.

43. In violation of his obligations under the agreements with Heartflow, Dr. Min did not disclose to Heartflow that he had incorporated Cleerly. Dr. Min did not seek Heartflow's consent to form a competing company. Dr. Min did not disclose any inventions to Heartflow that he conceived in connection with his services to Heartflow or applicable to the Field, which were assigned to Heartflow under the Consulting Agreement.

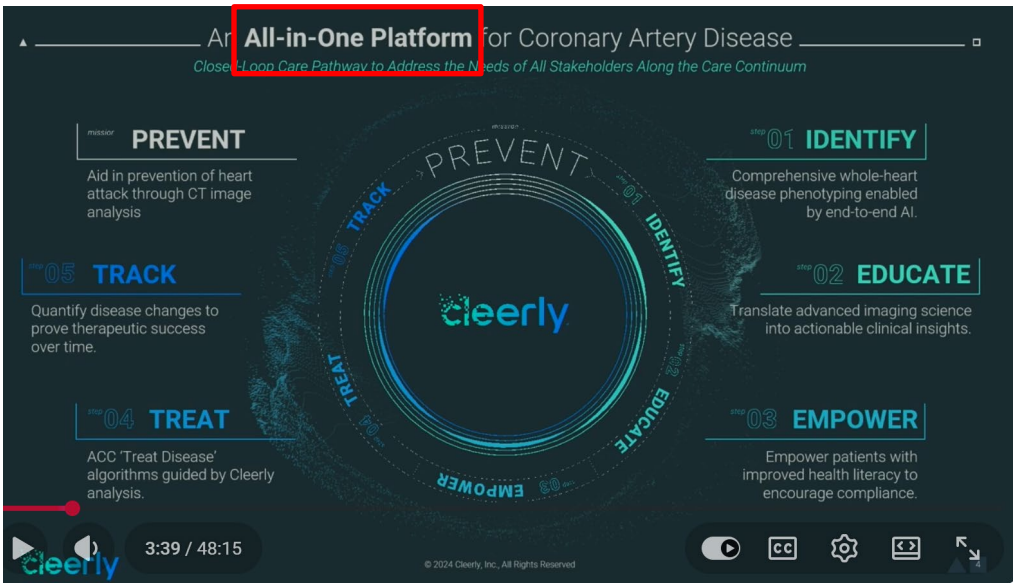
44. Dr. Min also did not disclose that he was a founder of Cleerly in any academic articles or journals at the time. Under the terms of the Consulting Agreement, Dr. Min was obligated to disclose these inventions to Heartflow and, in fact, under the agreement assigned them to Heartflow. Dr. Min secretly developed Cleerly's competing technology without disclosure to Heartflow.

45. On May 24, 2017, Dr. Min notified Heartflow of his termination of the Consulting Agreement, effective as of June 24, 2017, nearly one year after he had incorporated Cleerly. Dr. Min remained bound by the confidentiality provisions of the Consulting Agreement until eighteen months after termination, or December 24, 2019. Ex. 5 (Min Agreements).

46. In or around June 2017, Dr. Min was seeking funding for Cleerly while explaining that Cleerly's focus is to use machine learning on medical images to derive quantitative measures, which was in the same field as his work at Heartflow.

47. Upon information and belief, during the period from July 19, 2016 (when Dr. Min incorporated Cleerly) through December 24, 2019 (when his confidentiality obligations expired),

Dr. Min used Heartflow's Confidential Information to develop Cleerly's competing products, in direct violation of his contractual obligations to Heartflow, including repackaging Heartflow's "One Stop Shop" as Cleerly's "All-in-One Platform":



48. Cleerly sought approval from FDA in early 2019, five years after Heartflow obtained *de novo* clearance from FDA for its FFR_{CT} technology.

49. Riding Heartflow's coattails, Cleerly relies on the same billing code for its ISCHEMIA product as was approved by CMS based on Heartflow's application years earlier:

> ## Applying the Category I CPT® Code 75580 to Cleerly ISCHEMIA
>
> **Category 1 CPT® Code 75580:** "Noninvasive estimate of coronary fractional flow reserve derived from augmentative software analysis of the data set from a coronary computed tomography angiography, with interpretation and report by a physician or other qualified healthcare professional."
>
> https://cleerlyhealth.com/ischemia-reinvented

50. Upon information and belief, the inventions and technology underlying Cleerly's products were conceived by Dr. Min in connection with his services to Heartflow and/or are applicable to the Field defined in the Consulting Agreement. Dr. Min was obligated to disclose

these inventions to Heartflow and assign them to Heartflow. While Dr. Min did not disclose these inventions, by executing the Consulting Agreement—that states that Dr. Min "hereby assigns to the Company [Heartflow] all right, title and interest in and to any such Inventions, irrespective of whether such Inventions are disclosed"—Dr. Min executed an assignment of his inventions to Heartflow. Secretly developing Cleerly's competing technology without disclosure to Heartflow does not unburden Dr. Min and Cleerly of the invention assignment that has already occurred.

B. Dr. Min Actively Undermines Heartflow at Cornell

51. While Dr. Min was developing Cleerly without informing Heartflow, he was simultaneously working to undermine Heartflow's business at his own institution, Weill Cornell Medical College. Ex. 24 (Ellis Email).

52. Weill Cornell Medical College had been the first institution in New York to use Heartflow's FFRCT technology. *Id.* at 2. But Dr. Min worked to end that relationship. *Id.* at 3-4. In January 2018, Dr. George C. Ellis, a physician affiliated with Cornell, reached out to Dr. Min to inquire whether Cornell planned to "reconnect with Heartflow." *Id.* at 5. Dr. Ellis noted that Heartflow's technology offered patient benefits and had recently received approved reimbursement from Medicare and Blue Cross Blue Shield plans. *Id.* at 4. He observed that "other institutions are using Heartflow." *Id.*

53. Dr. Min's response was telling. Rather than acknowledge the clinical value of Heartflow's technology—technology he had helped validate and called "disruptive" and a "one stop shop" as principal investigator of the DeFACTO study—Dr. Min disparaged Heartflow's product by citing unspecified "logistical" and "performance related" reasons for Cornell's decision not to use it. *Id.* at 3. Then, critically, Dr. Min pivoted to promote his own competing venture: "there are some very new test types emerging, so if you have time in the near future, i'd love to speak to you about them." *Id*.

54. The "very new test types" Dr. Min was referring to were the products he was developing at Cleerly, the company he had incorporated eighteen months earlier while still under contract with Heartflow. *Id.* Dr. Min was using his position at Cornell not only to block Heartflow's access to a major academic medical center, but also to market his own competing technology to physicians who might otherwise have referred patients for Heartflow analysis, thereby blocking patient access to Heartflow's beneficial technology.

55. When Dr. Ellis forwarded this exchange to Heartflow's Chief Medical Officer, Dr. Campbell Rogers, Heartflow's leadership recognized immediately that Dr. Min's conduct was problematic and "may reflect some non-clinical aspects." *Id.* at 2. This conduct occurred while Dr. Min remained bound by the confidentiality provisions of his Consulting Agreement, which did not expire until December 2019.

C. Heartflow Confronts Cleerly: Cleerly's Counsel Misrepresents Cleerly's Activities

56. As Cleerly emerged from the shadows and began to market its competing products, Heartflow grew concerned that Dr. Min and Cleerly were violating the Consulting Agreement's restrictions, including the prohibition on developing products or services in the defined Field.

57. In June 2020, Heartflow's counsel wrote to Cleerly demanding assurances that Cleerly was complying with Dr. Min's contractual obligations. Heartflow specifically sought confirmation that Cleerly was not developing products or services within the Field defined in the Consulting Agreement, the Field that encompassed computational fluid dynamics for vascular flow assessment, lesion-specific ischemia evaluation, and therapeutic prediction modeling for coronary revascularization.

58. On June 26, 2020, Cleerly's attorney, Todd R. Gregorian of Fenwick & West LLP, responded to Heartflow's counsel. Ex. 25 (Cleerly Letter). In that letter, Mr. Gregorian made the following representation on Cleerly's behalf: "Cleerly has not developed, nor is it developing,

products or services in the Field, including any products or services for the direct assessment of lesion specific ischemia." *Id* (reproduced below).

> Cleerly will provide the confirmations that HeartFlow has requested in order to resolve this matter: (1) Cleerly has not used, nor is it using, the confidential information of HeartFlow; (2) Cleerly has not developed, nor is it developing, products or services in the Field, including any products or services for the direct assessment of lesion specific ischemia. To avoid any further misunderstandings between the parties on this point, however, Cleerly does currently operate in the field of coronary artery disease.

59. This representation was false. Cleerly was actively developing, and would subsequently launch, products that fall squarely within the Field. Most notably, Cleerly's "Cleerly ISCHEMIA" product, which uses AI algorithms to assess myocardial ischemia from CCTA images, is precisely a product for the "direct assessment of lesion specific ischemia" that Mr. Gregorian represented Cleerly was **not** developing.

60. Cleerly's website directly contradicts Cleerly's attorney's representation: "[t]he ability for Cleerly ISCHEMIA to provide this comprehensive lesion-by-lesion mapping within a vessel for the clinically actionable features of coronary artery disease can be used to support the care team in determining whether there may be a lesion to be considered for coronary revascularization and if so, to guide the care team to such relevant factors as ischemia, stenosis and atherosclerosis." https://cleerlyhealth.com/ischemia-reinvented (Ex. 26). In another example of a physician educational webinar, Cleerly promotes that "Attendees will learn how Cleerly ISCHEMIA supports lesion-specific assessment" and "Explore how Cleerly ISCHEMIA provides vessel-level insights, including lesion-specific characteristics." Ex. 27 (https://cleerlyhealth.com/webinars/ischemia-plaque). And the Cleerly ISCHEMIA algorithm is trained on lesions with stenosis and lesion length. Additionally, in a paper written by James Min and other Cleerly employees, they stated "The focus of this study is a novel AI-guided quantitative

computed tomography ischemia algorithm (AI-QCTischemia), comprising a machine-learned method that leverages features of atherosclerosis and vascular morphology from coronary CTA images to identify whether coronary lesions will likely cause myocardial ischemia." Ex. 53 (https://pmc.ncbi.nlm.nih.gov/articles/PMC11057943/).

D. Brent Ness: Former Heartflow Executive with Confidentiality Obligations

61. To continue to build upon Heartflow's know-how and innovation, Cleerly targeted Heartflow's Chief Commercial Officer and hired Brent Ness who had full access to Heartflow's clinical, technical, and business activities and had fiduciary and confidential obligations to Heartflow. Cleerly hired Mr. Ness, who had signed agreements foreclosing his use of Heartflow confidential information.

62. After leaving Heartflow, Mr. Ness joined Cleerly as President and Chief Commercial Officer from 2019 to 2021. Ex. 28 (MarketScreener, "Brent Ness: Positions, Relations and Network," https://www.marketscreener.com/insider/BRENT-NESS-A1I19C/).

63. Upon information and belief, after serving as President and Chief Commercial Officer, Mr. Ness continued to serve as a Consultant at Cleerly, where he played a key role in fundraising efforts. https://theorg.com/org/aclarion/org-chart/brent-ness.

64. Upon information and belief, Mr. Ness brought to Cleerly his intimate knowledge of Heartflow's technology, its patents, its commercial strategies, and its competitive advantages-knowledge that he obtained during his employment as Heartflow's Chief Commercial Officer and that he was obligated to keep confidential under the agreement between Heartflow and Mr. Ness. Upon information and belief, Cleerly used this confidential information to develop and market its infringing products.

E. The Combined Knowledge of Dr. Min, Mr. Ness, And Cleerly As a Whole Establishes Willfulness

65. Cleerly was founded by Dr. Min, who served as Heartflow's trusted consultant for five years, who executed an NDA and Consulting Agreement with Heartflow, who had access to Heartflow's most sensitive confidential information, who assigned inventions to Heartflow via his execution of the Consulting Agreement, and who secretly incorporated Cleerly while still under contract with Heartflow. Cleerly then hired Mr. Ness, Heartflow's former Chief Commercial Officer, who had full access to Heartflow's clinical, technical, and business activities and who was bound by confidentiality obligations under the Ness Agreement and Separation Agreement.

66. Through Dr. Min and Mr. Ness, Cleerly had actual knowledge of Heartflow's patents, Heartflow's trade secrets, Heartflow's confidential technical information, Heartflow's commercial strategies, and Heartflow's competitive positioning. This knowledge, coupled with Cleerly's decision to develop and commercialize directly competing products without seeking a license, constitutes willful infringement.

67. Cleerly's knowledge about Heartflow's patents, including the Asserted Patents, is readily apparent based on Cleerly repeatedly citing to Heartflow's patents on the faces of its own patents as shown below:

Heartflow's Patents	**Cleerly Patent Citing Heartflow's Patent**
US11288813B2	US11501436B2 US11642092B1 US11690586B2 US11861833B2 US11922627B2 US12144669B2 US12380560B2 US12440180B2
US11382569B2	US11642092B1 US11660058B2 US11690586B2 US11861833B2 US11922627B2

Heartflow's Patents	Cleerly Patent Citing Heartflow's Patent
	US12144669B2 US12380560B2 US12440180B2
US9770303B2	US10813612B2 US11094060B1 US11210786B2 US11861833B2 US11922627B2 US12144669B2 US12380560B2 US12440180B2
US9839399	US10813612B2 US11094060B1 US11210786B2 US11861833B2 US11922627B2 US12144669B2 US12380560B2 US12440180B2 US12555228B2
US11013425B2	US11113811B2 US11210786B2 US11317883B2 US11861833B2 US11922627B2 US12144669B2 US12380560B2 US12440180B2

F. Cleerly's Infringing Products

68. Cleerly develops AI-powered cardiac imaging analysis software that directly competes with Heartflow's patented technologies. Ex. 29 (Cleerly, https://cleerlyhealth.com/).

69. Cleerly's flagship offering is an AI-powered coronary computed tomography angiography ("CCTA") analysis platform that, like Heartflow's patented technology, uses artificial intelligence and machine learning algorithms to analyze CCTA images and provide physicians

with diagnostic information about coronary artery disease. (Cleerly, Inc., "What is Cleerly," https://cleerlyhealth.com/what-is-cleerly).

70. Cleerly's CCTA analysis products include:

- Cleerly Plaque Analysis uses AI to analyze CCTA images and characterize coronary artery plaque—including low-density non-calcified plaque, non-calcified plaque, calcified plaque, total plaque burden-functionality, and stenosis detection—and directly competes with Heartflow's Plaque Analysis and Roadmap Analysis.

- Cleerly ISCHEMIA uses AI algorithms to assess myocardial ischemia from CCTA images-functionality—and directly competes with Heartflow's FFR_{CT} Analysis.

- Cleerly COMPARE uses AI to provide longitudinal disease evaluation.

71. These products fall within the "Field" defined in Dr. Min's Consulting Agreement with Heartflow: "(a) computational fluid dynamics for assessment of vascular flow, (b) direct assessment of lesion specific ischemia, and (c) therapeutic prediction modeling of coronary revascularization, including medical, percutaneous and surgical." At the time Dr. Min was a consultant with Heartflow, the company was well underway with active research, development, and inventions related to AI analysis of coronary anatomy, plaque, and lesion-specific ischemia as part of building a product in this field. Upon information and belief, Dr. Min conceived of these products, or the inventions underlying them, in connection with his services to Heartflow. Pursuant to the language of the Consulting Agreement, irrespective of Dr. Min's failure to disclose these patents, they are assigned to Heartflow.

72. Upon information and belief, Cleerly's products employ AI algorithms, image processing techniques, coronary artery segmentation methods, plaque characterization

technologies, and blood flow analysis methods that are covered by one or more claims of Heartflow's patents.

NATURE OF THE ACTION, JURISDICTION, AND VENUE

73. Heartflow brings this action for patent infringement under the patent laws of the United States, 35 U.S.C. § 271 *et seq*.

74. This Court has subject matter jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§ 1331 and 1338(a) because the action arises under the patent laws of the United States.

75. This Court has personal jurisdiction over Cleerly because Cleerly has committed acts of patent infringement within this judicial district, has conducted business in this judicial district, has purposefully directed activities at residents of this judicial district, and has purposefully availed itself of the privileges of conducting business in Texas such that Cleerly should reasonably anticipate being haled into court in this judicial district, including by sales, service, and maintenance of accused products and services in this judicial district, and inducing others to commit acts of patent infringement in this judicial district.

76. Cleerly has established a significant physical presence in Texas, including the Eastern District of Texas, by establishing regular places of business in this District.

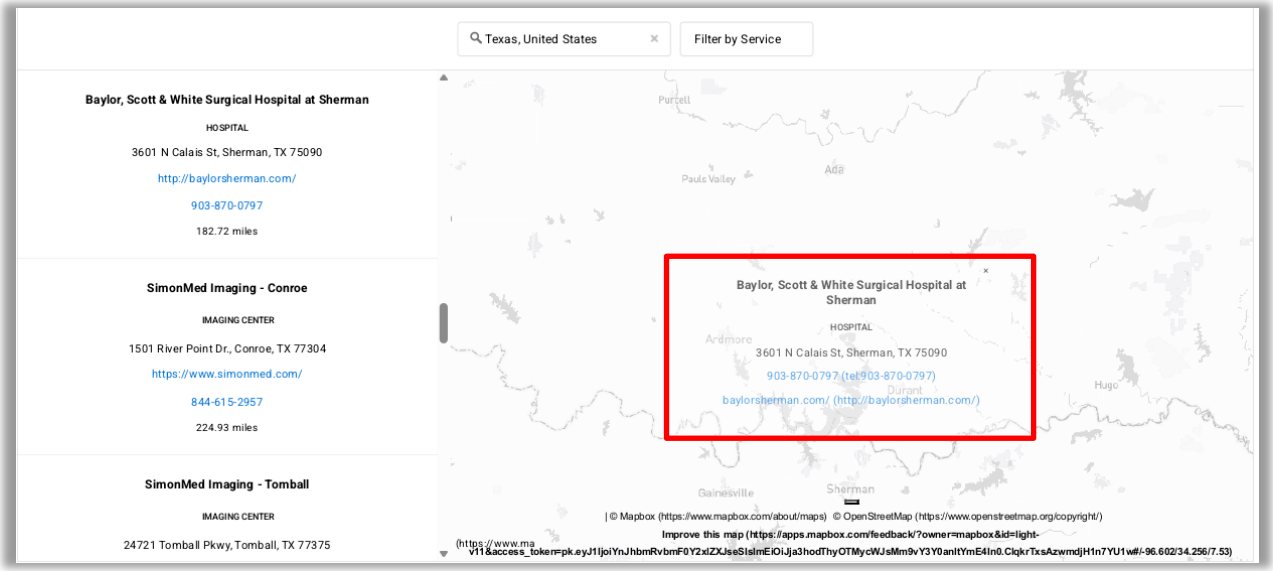
77. Upon information and belief, Cleerly operates regular places of business of "Cleerly heart scan imaging locations" across the Eastern District of Texas that offer Cleerly's services to patients. Ex. 30 (Cleerly, Inc., "Find Cleerly Near You," https://cleerlyhealth.com/find-cleerly-near-you). Cleerly's physical places of business are located at the following addresses in this District:

North Star Diagnostic 3700 W 15th St. Bldg D, Suite 200, Plano, TX 75075	Baylor Scott & White The Heart Hospital – Plano 1100 Allied Dr, Plano, TX 75093

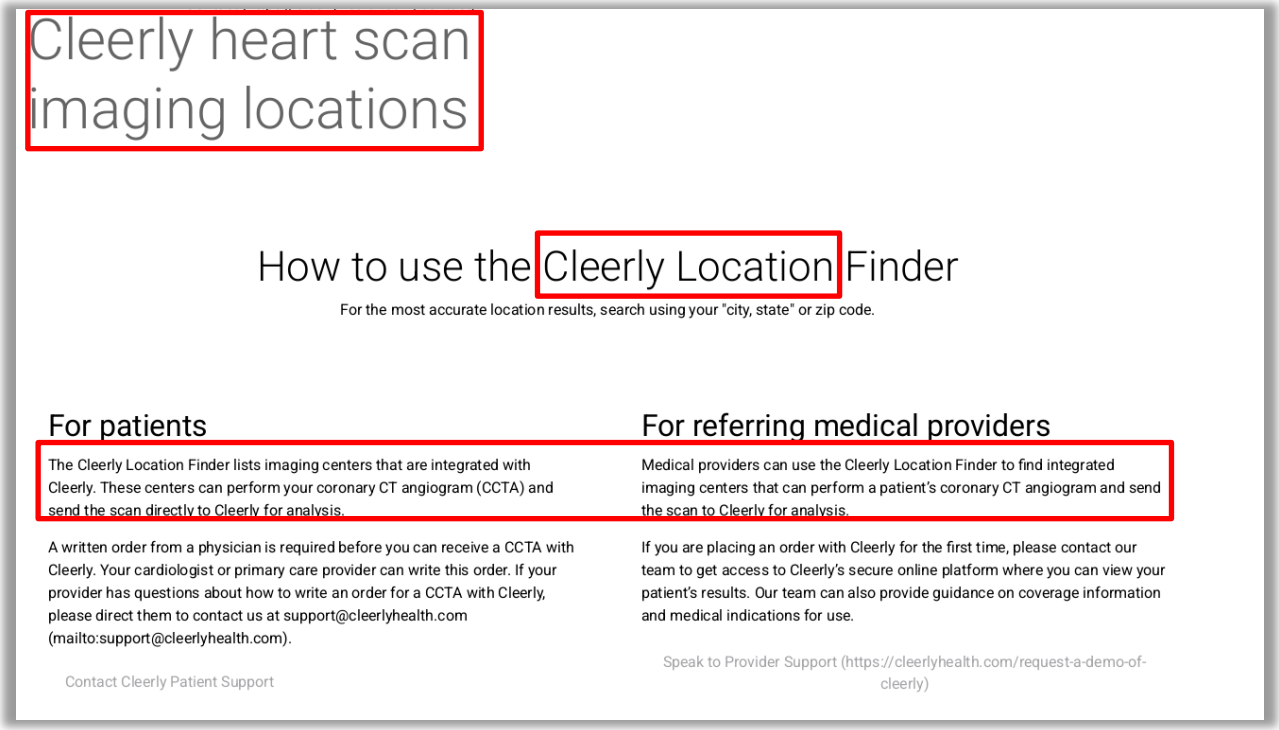
The Heart Hospital Baylor Plano Center for Advanced Cardiovascular Care (CACC) 4716 Alliance Blvd Ste 300, Plano, TX 75093	Baylor Scott & White Legacy Heart Center - Plano Preston Road 6601 Preston Rd, Plano, TX 75024
Baylor, Scott & White Medical Center – Centennial 12505 Lebanon Rd, Frisco, TX 75035	Envision Radiology Imaging of Plano 6957 W Plano Pkwy Suite 1100, Plano, TX 75093
Baylor Scott & White The Heart Hospital - Plano 1100 Allied Dr, Plano, TX 75093	Baylor, Scott & White Surgical Hospital at Sherman 3601 N Calais St, Sherman, TX 75090
Baylor Scott & White Medical Center – McKinney 5252 W University Dr, McKinney, TX 75071	Baylor Scott & White The Heart Hospital – Denton 2801 S Mayhill Rd, Denton, TX 76208

78. Cleerly's website lists all these locations on its website "https://cleerlyhealth.com/find-cleerly-near-you" and explains that "Cleerly heart scan imaging locations" can be found by patients in this District at these addresses. Cleerly provides contact information for each of these physical locations on its website.

79. Cleerly promotes these Eastern District locations on its website alongside its other imaging centers in Texas and around the country, directing both patients and health care providers to Cleery's heart scan imaging centers. *Id.*



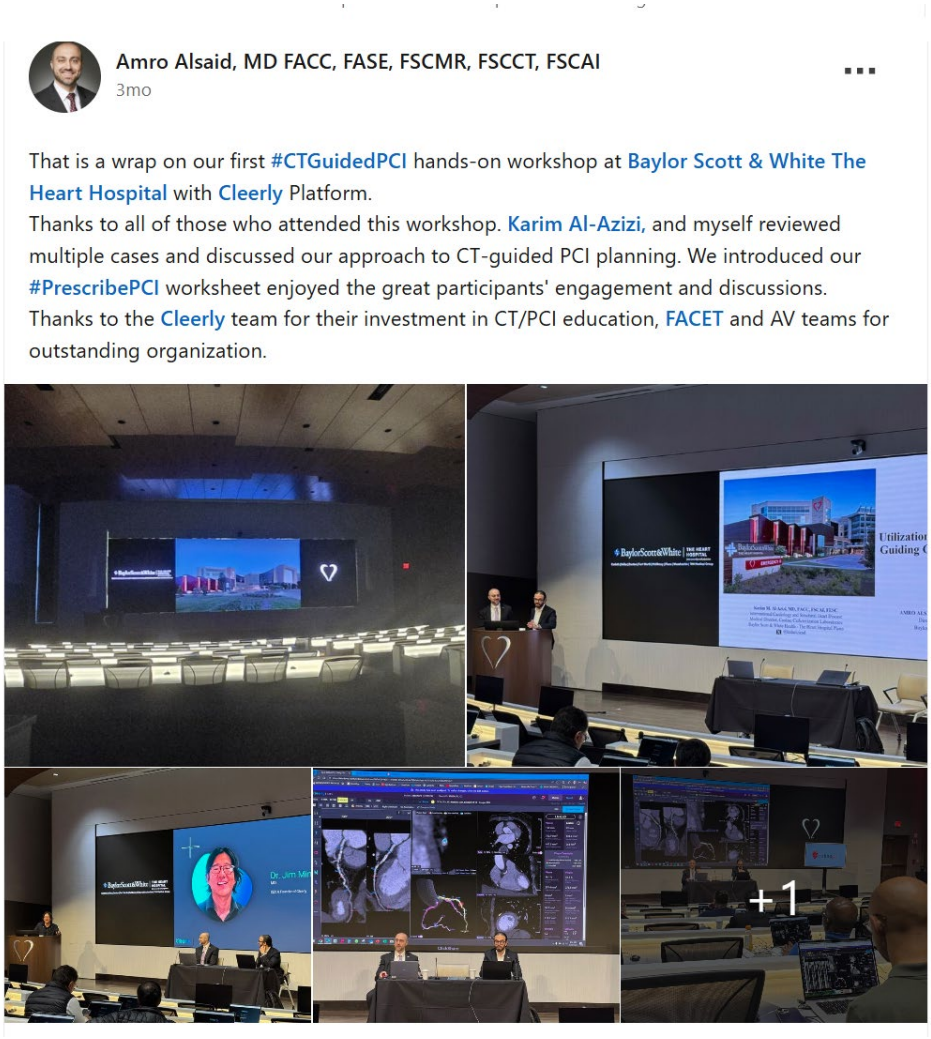
Id. (showing "Cleerly Location" in this judicial district and other locations in Texas).



Id. (directing both patients and medical providers to "imaging centers that are integrated with Cleerly" in this judicial district and other locations in Texas).

80. Upon information and belief, Cleerly employs at least seven employees in Texas. Ex. 32 (CapIQ Report on Cleerly). Upon information and belief, these employees maintain a regular presence at "Cleerly heart scan imaging locations" for providing training to clinical, administrative and technology teams. Cleerly heart scan imaging locations are not passive referral sites; they are extensions of Cleerly's business operations. Cleerly provides "customized workflow integration to meet [the centers'] administrative, technology, and billing workflow needs" and provides "training for clinical, administrative, and technology teams." Ex. 34 (Cleerly Imaging Center Brochure, https://cleerlyhealth.com/hubfs/customer-marketing-resources/brochures/cleerly-imaging-center-brochure.pdf). Upon information and belief, Cleerly dispatches its employees regularly to each integrated imaging center to establish and maintain this integration and to train center personnel.

81. For example, one of these integrated imaging centers is located at Baylor Scott & White Surgical Hospital at Sherman, Texas—squarely within the Eastern District of Texas. *Id.* At Cleerly's regular place of business in Baylor Scott & White The Heart Hospital in this District (1100 Allied Dr, Plano, TX 75093), Cleerly's employees including the CEO—Dr. Min—regularly and extensively provide training to medical professionals by using Cleelry equipment to enable professionals in this District to use the infringing products and provided infringes services:



https://www.linkedin.com/posts/amroalsaid_ctguidedpci-prescribepci-activity-7416513113858105346-9t-z?

82. When health care providers perform a "Cleerly scan," they do so for the purpose of obtaining a Cleerly analysis. Ex. 35 (Cleerly Patient Education, https://cleerlyhealth.com/patient-education). As part of Cleerly's analysis, the patient's health care provider refers the patient to obtain a coronary computed tomography angiography ("CCTA") scan. *Id.* The imaging data is analyzed by Cleerly's AI algorithms, which include the same algorithms that infringe Heartflow's patents. Upon information and belief, the integrated imaging centers and affiliated providers function as Cleerly's agents in delivering Cleerly's infringing technology to patients.

83. Upon information and belief, Cleerly exercises control over the activities of Cleerly heart scan imaging locations by ensuring that the CT angiograms are conducted based on Cleerly's instructions and sent directly to Cleerly software for analysis. Further, Cleerly holds out to the public including customers and medical providers that Cleerly's services can be obtained in this District by going to the physical locations of Cleerly heart scan imaging locations.

84. On its website, Cleerly advertises to its customers and medical providers that Cleerly heart scan imaging locations provide Cleerly services at these locations. The Cleerly website identifies the physical locations on its website as "Cleerly heart scan imaging locations" and explains that a user can locate Cleerly by using the "Cleerly Location Finder." In addition, Cleerly's marketing materials hold out its imaging locations as being part of Cleerly.

85. Upon information and belief, Cleerly provides ISCHEMIA and Cleerly Scan brochures and presentations to its Cleerly heart scan imaging locations for distribution to patients and medical providers. Upon information and belief, such materials prominently display Cleerly's branding. Cleerly presents its Cleerly heart scan imaging locations, as an extension of itself.

86. Upon information and belief, Cleerly maintains equipment including proprietary software and/or additional terminals to provide Cleerly heart scan reports and services at the

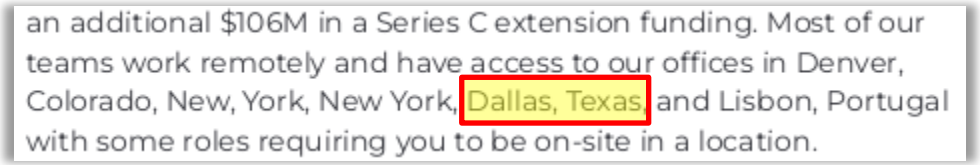
Cleerly heart scan imaging locations. Cleerly has no apparent alternative method to conduct its business except through sending patients, medical providers, and its employees for training the medical staff to Cleerly heart scan imaging locations, including in this District. These Cleerly heart scan imaging locations are a direct and integral part of the diagnostic process for the accused Cleerly products. Without them, Cleerly's business model, including obtaining payments from patients and delivery of the results of the patient diagnosis based on steps performed by the infringing product collapses. Cleerly's business is conducted in this District by its employees and its agents at the Cleerly heart scan imaging centers at Cleerly's direction.

87. Upon information and belief Cleerly has also entered into commercial agreements with health care providers operating within this District and Texas to provide its AI-powered CCTA analysis services, such as the one they entered into with Texas C3 Heart Experts, a cardiology practice that utilizes "AI-driven programs such as Heartflow, Cleerly, and Elucid" as part of its advanced imaging services. Ex. 33 (Texas C3 Heart Experts, https://www.texasc3.com/c3heartexperts/). Upon information and belief, Cleerly has entered into similar agreements with additional hospitals and medical facilities in this District, including the Clearly heart scan imaging centers identified herein.

88. Cleerly maintains an interactive, commercial website at https://cleerlyhealth.com/, through which it markets its products and services to health care providers and patients nationwide, including those located in the Eastern District of Texas.

89. Cleerly website includes a "Find Cleerly Near You" feature that specifically directs patients and providers to Cleerly's integrated imaging centers in, among other locations, Sherman, Plano, McKinney, Denton and Frisco Texas. Ex. 30 (Cleerly, Inc., "Find Cleerly Near You," https://cleerlyhealth.com/find-cleerly-near-you).

90. Upon information and belief, Cleerly also maintains an office in Dallas, Texas as it advertises on its website for prospective employees and has its employees from this office regulary visit the places of business in this District. Ex. 31 (BuiltIn, Cleerly Job Posting, https://builtin.com/job/analyst-portugal/2628989) (reproduced below).


an additional $106M in a Series C extension funding. Most of our teams work remotely and have access to our offices in Denver, Colorado, New, York, New York, Dallas, Texas, and Lisbon, Portugal with some roles requiring you to be on-site in a location.

91. Venue is proper in this judicial district as to Cleerly pursuant to 28 U.S.C. § 1400(b) because Cleerly has committed acts of infringement in this District and has a regular and established places of business in this District.

92. Cleerly has physical places of business in this district that it has ratified and that is regular and established. As noted above, Cleerly conducts business at multiple integrated imaging centers within the Eastern District of Texas, include locations in Sherman, Plano, Frisco, McKinney, and Denton, Texas. Cleerly lists these physical locations on its website its imaging centers that are integrated with Cleerly and that offer Cleerly technology. Ex. 36 (Craft Concierge, "7 Reasons to Get a Cleerly CT Angiogram Scan for Your Heart Health," https://craftconcierge.com/blog/7-reasons-to-get-a-cleerly-ct-angiogram-scan-for-your-heart-health/) ("Find a nearby imaging center that offers Cleerly technology").

93. Cleerly has ratified these locations as its own places of business in this district. Cleerly's integrated imaging centers are not mere passive referral sites; they are extensions of Cleerly's business operations where Cleerly's infringing technology is deployed and where Cleerly provides ongoing support, training, and workflow integration. Ex. 34 (Cleerly Imaging Center Brochure, https://cleerlyhealth.com/hubfs/customer-marketing-

resources/brochures/cleerly-imaging-center-brochure.pdf). Cleerly provides customized administrative, technology, and billing workflow integration at each center and trains clinical, administrative, and technology teams. *Id.* Upon information and belief, Cleerly dispatches employees to the Cleerly heart scan imaging centers – including those in Sherman, Plano, Denton, Frisco and McKinney, Texas – to establish and maintain these integrations and train center personnel.

94. The places of business are regular and established. Cleerly's website lists its Eastern District of Texas imaging center in the same manner as it lists all of its other imaging centers nationwide, with no distinction in the services offered. Ex. 30 (Cleerly, Inc., "Find Cleerly Near You," https://cleerlyhealth.com/find-cleerly-near-you). Cleerly directs both patients and health care providers to this Eastern District location for Cleerly scans and analyses. *Id.*

95. Additional evidence that Cleerly has a place of business in Texas and conducts infringing activities and benefits from such infringing acts in Texas is included below:

Texas Taxpayer Number:
32088369080

Texas SOS File Number:
0804920615 (registration effective as of February 9, 2023)

Address of Registered Texas Agent:
5900 Balcones Drive, Suite 100, Austin, TX 78731

https://comptroller.texas.gov/taxes/franchise/account-status/search/32088369080.

ASSERTED PATENTS AND TECHNICAL INNOVATIONS THEREOF

96. The Asserted Patents are U.S. Patent Nos. 11,288,813 (Ex. 7), 11,382,569 (Ex. 8), 9,770,303 (Ex. 9), 9,839,399 (Ex. 10), 9,607,386 (Ex. 11), and 11,013,425 (Ex. 12).

97. As noted above and incorporated herein by reference, each of the Asserted Patents and the claimed inventions thereof are directed to "novel," "groundbreaking," "disruptive,"

"innovative," and "new" technologies that did not have a predicate device. These innovations and distinctions over routine and conventional techniques were recognized by the FDA, CMS, Cleerly's founder and CEO, and many others in the industry. *See* paragraphs 17-41.

98. As noted above and incorporated herein by reference, each of the Asserted Patents and the claimed inventions thereof are directed to novel and technically innovative technologies as recognized by the repeated citations of these patents by Cleerly on its own patents. *See* paragraph 67.

99. Further, each of the Asserted Patents and the claimed inventions thereof are directed to novel and technically innovative technologies as recognized by the repeated citing of these patents by many entities operating in the field of medical devices, including, for example, Siemens Medical Solutions USA, Inc., Emory University, Elucid Bioimaging Inc. and Cleerly.

100. Further, during prosecution of its patent applications, Cleerly admitted that claims directed to similar subject matter—but with later priority dates—are directed to patent-eligible inventions. These statements also apply to the claims of the Asserted Patents.

101. For example, during the prosecution of Cleerly patent application (U.S. Patent Application No. 18/531,500) with a much later alleged priority date of March 10, 2022, Cleerly represented to the U.S. Patent and Trademark Office (USPTO) that claimed methods that rely on machine learning algorithms, such as a convolutional neural network (CNN), provide "technical improvements" in the field of coronary artery disease. *See* Exhibit 37 (Amendment filed by Cleerly in U.S. Patent Application no. 18/531,500, dated December 26, 2024). Cleerly made the following representations and provided the following party admissions:

- "claimed methods utilizing convolutional neural network provide various technical improvements in the field of determination of risk of coronary artery disease (CAD)." *Id.*

- "The use of machine learning algorithm, specifically a CNN, automates the analysis process, reducing human error and providing consistent results." *Id.*

- "[A]utomated analysis can use large volumes of medical images to identify patterns efficiently (e.g., thousands of medical images), which would be impossible for a human mind to analyze within a reasonable amount of time."

- "Additionally, CNNs are capable of automatically extract[ing] relevant features from images without the need for manual feature engineering. This capability allows the claimed methods to identify subtle and complex patterns in plaque that are not possible to identify by traditional methods." *Id.*

- "The use of multiple layers in the CNN, with each layer comprising overlapping clusters of nodes, enhances the network's ability to learn hierarchical representations of the image data, improving the accuracy and robustness of plaque shape determination." *Id.*

- These "features and other feature support a finding of eligibility at Step 2A, Prong Two at least because they provide an improvement to technology related to determination of risk of coronary artery disease (CAD) using machine learning." *Id.*

102. During the prosecution of another patent application (U.S. Patent Application no. 17/647,310) with a later alleged priority date of January 7, 2020, Cleerly provided the following representations and party admissions:

- "A person cannot simply look at a non-invasively obtained medical image of a coronary region and generate a determination of ischemia or a score for the risk of CAD based on vascular morphology parameters, plaque parameters, and/or presence or risk of stenosis. Such calculations are too complex to be performed entirely by the human mind." *See* Exhibit 38 (Amendment filed by Cleerly in U.S. Patent Application no. 17/647,310, dated May 30, 2023).

- "[D]etermining plaque parameters is nearly impossible to perform in the human mind and/or with the aid of pen/paper. One cannot simply draw a consistent line around a volume of plaque distinguishing plaque features in each pixel." *Id*.

- "One cannot simply determine ischemia based on non-invasively obtained images in one's head." *Id.*

- "[C]laims, such as in the element of 'generating a weighted measure of the vascular morphology parameters, plaque parameters, presence or risk of stenosis, and presence or risk of ischemia,' amount to technical improvements over a routine implementation of any potential abstract idea." *Id.*

- "[T]he transformation of that raw data [medical image] into a particular determination of a graphical representation or determination of 'a presence or risk of stenosis,' 'a presence or

risk of ischemia,' and ultimately an 'assessment of risk of CAD' is 'sufficient to render th[e] . . . narrowly-claimed process patent-eligible.'" *Id*.

- "[T]he human mind cannot use a machine learning algorithm that 'comprises a convolutional neural network trained on a set of medical images in which regions of plaque have been identified." *See* Exhibit 39 (Amendment filed by Cleerly in U.S. Patent Application no. 17/647,310, dated March 1, 2024).

103. During the prosecution of another patent application (U.S. Patent Application no. 18/591,778) with a later alleged priority date on or around May 2022, Cleerly provided the following representations and party admissions:

- "Modern medical images-such as those generated by CT, MRI, or PET scans-typically comprise hundreds or thousands of high-resolution slices, with each slice containing millions of pixels or voxels. As a result, selectively identifying a volume of interest within such a dataset requires processing and interpreting a substantial amount of information, which is well beyond what the human mind can accomplish mentally, with or without a physical aid." *See* Exhibit 40 (Amendment filed by Cleerly in U.S. Patent Application no. 18/591,778, dated July 15, 2025).

- "[A]ssessing the volume of interest to determine a mapped plaque density distribution for each pixel or voxel requires quantitative analysis of millions of data points." *Id.*

- "As a practical matter, the human mind cannot perform such high-volume, high-precision assessments without the assistance of specialized computer systems." *Id.*

- "[C]omparing a current volumetric assessment to one or more pre-existing medical image assessments requires not only storing and recalling massive datasets, but also conducting complex, multi-dimensional computations. Thus, due to the sheer volume and complexity of the data involved," such features "cannot be performed by the human mind." *Id.*

- "[A]n unconventional improvement to the functions of a computer, or other technological field" include "a particular way to achieve the desired outcome of optimizing computational resource allocation in medical image analysis systems by performing quantitative volumetric assessment and high-dimensional feature mapping to proactively determine whether a newly acquired medical image (e.g., CT scan) corresponds to a previously analyzed image." *Id.* Such techniques "eliminat[e] the need for redundant execution of computationally intensive image processing and analysis for the new image." *Id.*

104. The above admissions by Cleerly, numerous citations to the Asserted Patents by medical device entities including on the faces of their own patents, industry praise including by

Cleerly's Founder and CEO, commercial success, FDA *de novo* approval, *i.e.*, "De Novo classification for novel devices," and Centers for Medicare and Medicaid Services' decision to assign "New Technology Ambulatory Payment Classification" confirm that claims of the Asserted Patents are patent-eligible for being directed to an inventive concept, present a technical improvement and innovation, and are not directed to well-understood, routine, and conventional techniques.

COUNT 1 – CLEERLY'S INFRINGEMENT OF U.S. PATENT NO. 11,288,813

105. Heartflow incorporates all preceding paragraphs by reference.

106. U.S. Patent No. 11,288,813 (the "'813 Patent") was duly issued on March 29, 2022, and is titled "Systems and methods for anatomic structure segmentation in image analysis." A copy of the '813 Patent is attached as Exhibit 7.

107. Heartflow is the owner by assignment of the '813 Patent and possesses all rights under the '813 Patent, including the exclusive right to recover for past and future infringement.

108. The '813 Patent is directed to a computer-implemented method, system, and/or computer-readable medium of anatomic structure segmentation in image analysis. For example, the '813 Patent discloses a system having at least one memory and processor executing instructions and/or a method for receiving first image data of an anatomic structure of a patient, obtaining an estimate of a boundary of the anatomic structure, determining a centerline of the anatomical structure, extracting a plurality of frames from the received first image data, each successive frame in the plurality of frames defining a respective plane orthogonal to the centerline and intersecting the centerline at a respective successive point along a length of the centerline, and each frame formed from a plurality of pixels or voxels, determining, in each frame, a center point of the anatomic structure based on the intersection of the centerline and the respective plane, generating,

using a trained convolutional neural network (CNN), predictions of a plurality of locations of the boundary of the anatomic structure in the first image data based on the first image data, the determined center points of each of the frames, and the estimation of the boundary of the anatomic structure, wherein the trained CNN is configured to perform a regression of intensity values of the pixels or voxels in the plurality of frames along each of a plurality of radial angular directions out from each center point to generate the predictions of the plurality of locations of the boundary of the anatomic structure in the first image data.

109. The ’813 Patent also discloses that the learned association is based on a further regression of intensity values of pixels or voxels in a plurality of frames in the second image data along each of the plurality of radial angular directions out from one or more center points of each frame of the second image data and that the regression is a continuous regression.

110. The ’813 Patent also discloses that each frame corresponds to a respective segment of the anatomic structure and the estimation of the boundary of the anatomic structure is in a format of a mesh, a voxel, an implicit surface representation, or a point cloud. Further, the anatomic structure comprises a blood vessel. The ’813 Patent also discloses that the boundary is associated with a vessel lumen boundary, a vessel lumen surface, or a combination thereof and that the predictions of the plurality of locations of the boundary of the anatomic structure have a sub-pixel or sub-voxel accuracy.

111. The ’813 Patent explains that, at the time of its priority date, a commonly used approach to partitioning an image into multiple segments was to automate the process using a convolutional neural network (CNN), which is trained to predict a class label for each image element, such as a pixel or voxel. ’813 Patent at 1:29-34. However, the segmentation boundary of such CNNs was accurate only up to the level of an image element, and a quantization error was

introduced by placing the segmentation boundary at pixel or voxel locations. *Id.* at 1:44-48. Additionally, although it may be known that a structure of interest does not contain holes and exists as one connected component, these assumptions could not be integrated into the CNN, such that the predicted labels could have spurious components and holes in the segmented objects. *Id.* at 1:48-53. Thus, there was a desire to build models such as CNNs that could achieve sub-pixel or sub-voxel accurate segmentations and could predict labels for single connected components without holes or disconnected structures. *Id.* at 1:54-57.

112. The ’813 Patent solved these problems by providing systems and methods for accurate prediction of segmentation boundary locations, including both a training phase and a testing phase to estimate a segmentation boundary with sub-pixel or sub-voxel accuracy. *Id.* at 3:35-47. More specifically, the claimed invention receives first image data of an anatomic structure of a patient, obtains an estimate of a boundary of the anatomic structure, and determines a centerline of the anatomical structure. These methods are especially useful for analysis of coronary arteries or other vessels, where the vessels are generally long, tubular structures with circular-like boundaries and a centerline down the middle of the vessel.

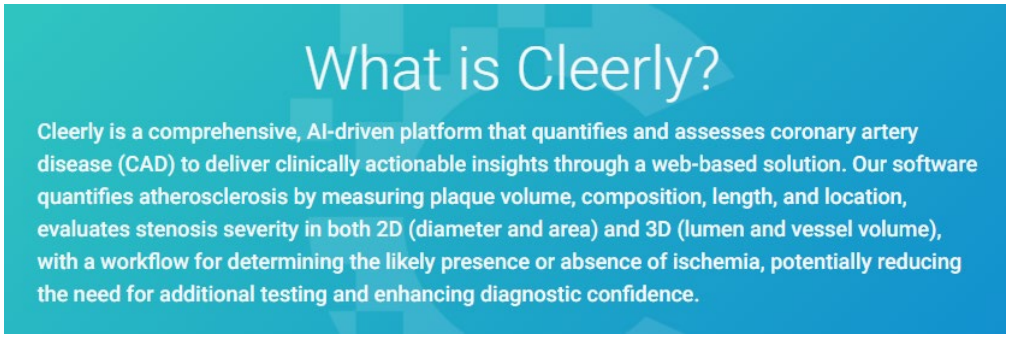
113. The claimed invention then extracts a plurality of frames from the received first image data, where each successive frame defines a respective plane orthogonal to the centerline and intersects the centerline at a respective successive point along a length of the centerline, and each frame is formed from a plurality of pixels or voxels. In each frame, a center point of the anatomic structure is determined based on the intersection of the centerline and the respective plane. Accordingly, a trained convolutional neural network (CNN) generates predictions of a plurality of locations of the boundary of the anatomic structure in the first image data, based on the first image data, the determined center points of each of the frames, and the estimation of the

boundary of the anatomic structure, wherein the trained CNN performs a regression of intensity values of the pixels or voxels in the plurality of frames along each of a plurality of radial angular directions out from each center point. Therefore, a computer-implemented method for anatomic structure segmentation that achieves sub-pixel or sub-voxel accurate predictions of boundary locations is achieved.

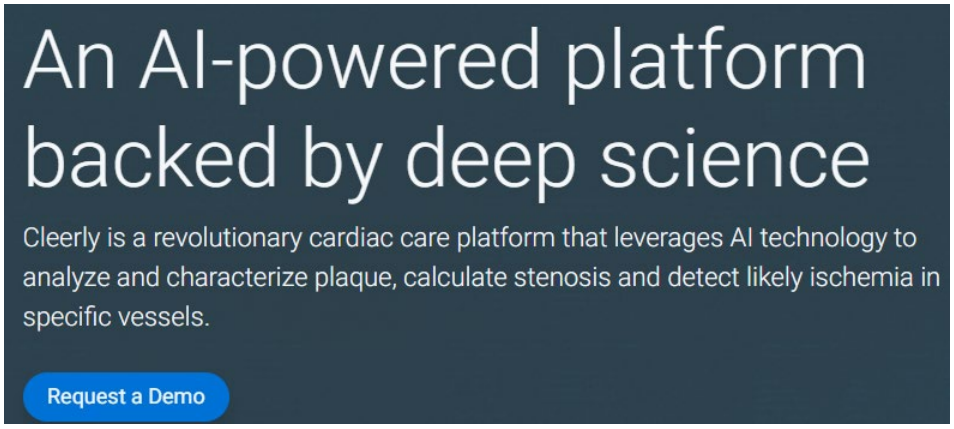
114. Evidence that the ’813 Patent is valid and is directed to novel and inventive technology is discussed above in at least paragraphs 17-41 and 96-103 and incorporated by reference. Further, the ’813 Patent has been recognized as a foundational patent as shown by the fact that it has been cited in over 61 additional patents, including patents filed by The Johns Hopkins University, Cleerly, and Cathworks.

115. Upon information and belief, Cleerly has directly infringed, and continues to directly infringe, literally and/or under the doctrine of equivalents, one or more claims of the ’813 Patent, including at least Claims 1, 3, 4, 6-8, 10-13, 15, and 17-19 by making, using, selling, and/or offering to sell into the United States products and services that practice the inventions claimed therein, including, but not limited to, one or more of Cleerly Plaque Analysis, Cleerly ISCHEMIA, and Cleerly COMPARE (“the Accused ’813 Cleerly Products”). Cleerly’s entire platform relies on creating this model of the coronary arteries using these infringing methods. For example, Cleerly provides a “comprehensive, AI-driven platform that quantifies and assesses coronary artery disease (CAD)” that “quantifies atherosclerosis by measuring plaque volume, composition, length, and location, evaluates stenosis severity in both 2D (diameter and area) and 3D (lumen and vessel volume), with a workflow for determining the likely presence or absence of ischemia.” https://cleerlyhealth.com/ (Ex. 29). Cleerly specifically claimed in a letter to Medicare that “Cleerly quantifies and characterizes sub-voxel (3D pixel)-level data from CCTA scans”

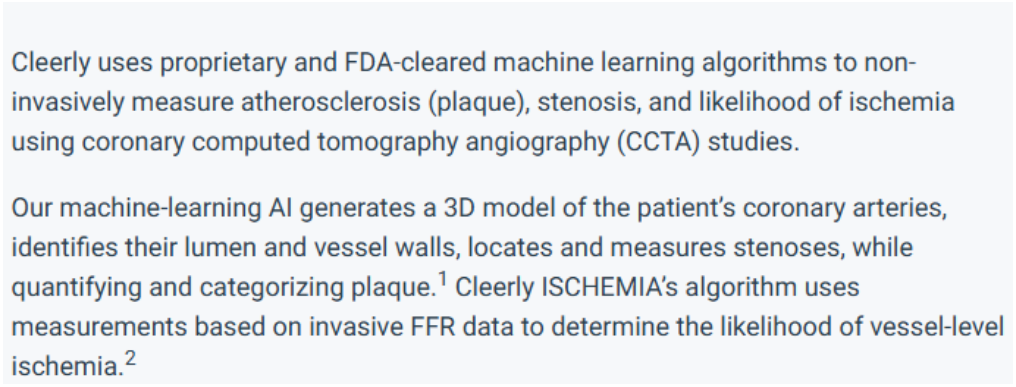
https://www.cms.gov/medicare-coverage-database/attachments/lcd/39850_2/PalmettoGBANewLCDRequest.pdf.



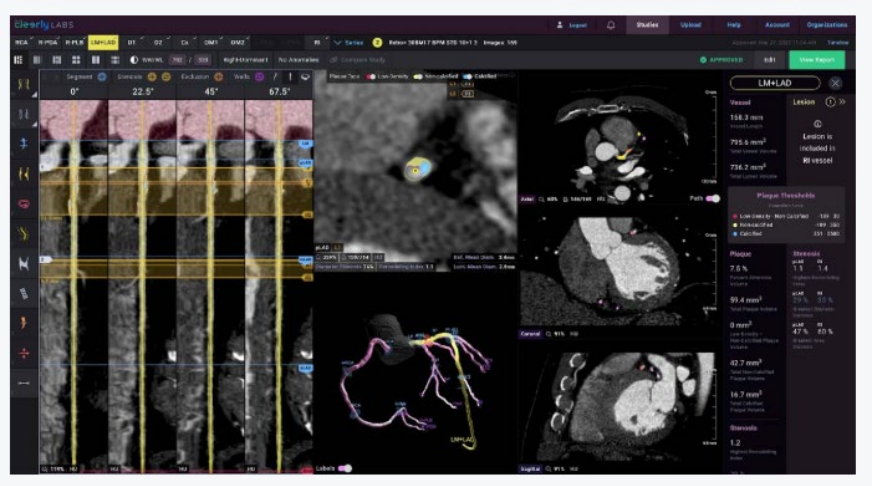
https://cleerlyhealth.com/ (Ex. 29)



https://cleerlyhealth.com/what-is-cleerly (Ex. 41)



https://cleerlyhealth.com/what-is-cleerly (Ex. 41)



https://cleerlyhealth.com/what-is-cleerly (Ex. 41)

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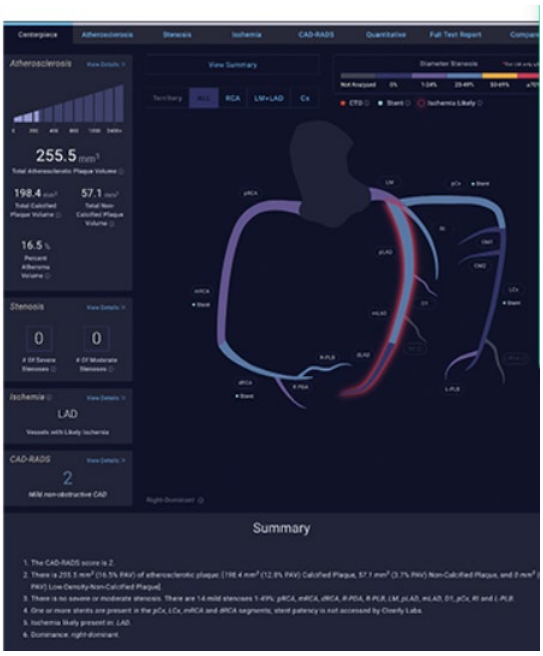
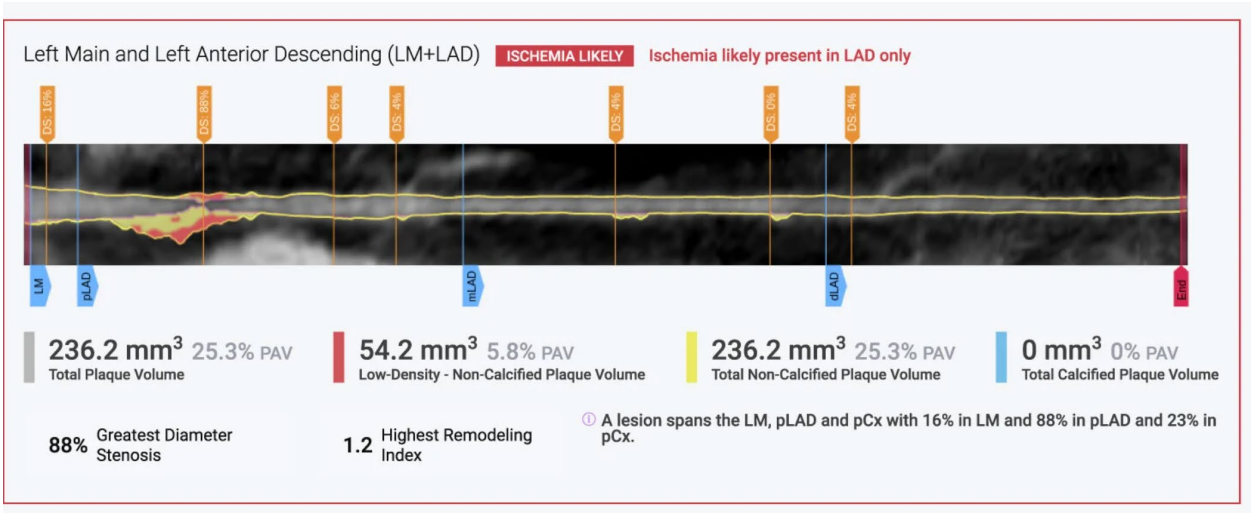


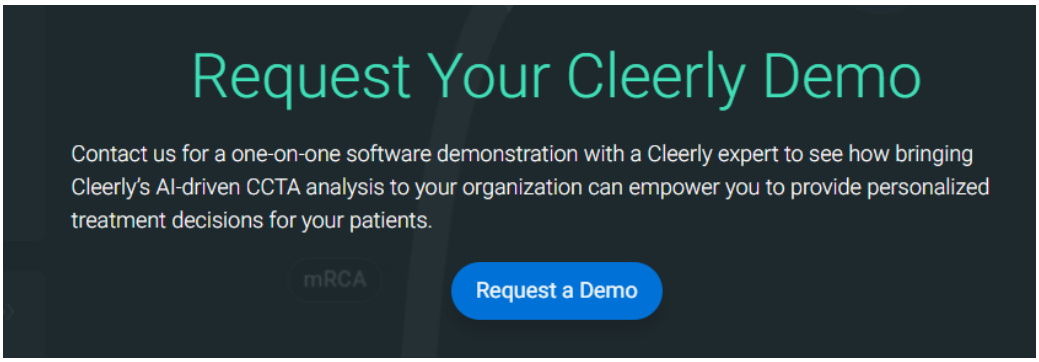
https://cleerlyhealth.com/what-is-cleerly (Ex. 41)



https://cleerlyhealth.com/patient-education (Ex. 35)

116. Heartflow reserves the right to discover and pursue any additional infringing products and services that incorporate infringing functionalities. For the avoidance of doubt, the Accused '813 Cleerly Products are identified to describe Cleerly's infringement and in no way limit the discovery and infringement allegations against Cleerly concerning other products that incorporate the same or reasonably similar functionalities.

117. Upon information and belief, Cleerly directly infringes by performing one or more method claims in the United States when, for example, performing testing, including "usability tests" as confirmed in FDA submissions, generating tutorial videos for training purposes, training hospital employees, conducting webinars, conducting demos at events, and/or producing instructional videos showing how the Accused '813 Cleerly Products operate. https://www.youtube.com/@cleerlyhealth/videos (Ex. 42); https://cleerlyhealth.com/clinical-publications; https://cleerlyhealth.com/blog; https://cleerlyhealth.com/webinars; https://cleerlyhealth.com/events.



118. Each of the Accused '813 Cleerly Products, either alone or in combination with each other, perform a computer-implemented method or implement a system and/or computer-readable medium of anatomic structure segmentation in image analysis.

119. For example, at least Claim 1 requires "receiving first image data of an anatomic structure of a patient." Upon information and belief, Cleerly receives coronary computed tomography angiography (CCTA) image data of a patient's coronary arteries. Ex. 41 (What is Cleerly, https://cleerlyhealth.com/what-is-cleerly). Cleerly's software analyzes these CCTA images using "machine learning algorithms to non-invasively measure atherosclerosis (plaque), stenosis, and likelihood of ischemia." *Id.* For example, the platform in the Accused '813 Cleerly

Products receives serial CCTA image data at multiple time points to enable analysis of plaque progression or regression over time. *Id.*

120. At least Claim 1 also requires obtaining an estimate of a boundary of the anatomic structure. Upon information and belief, Cleerly's deep learning algorithm performs automated "vessel wall and lumen segmentation," which necessarily involves obtaining an estimate of the coronary vessel lumen boundary. Ex. 43 (Griffin et al., AI Evaluation of Stenosis on Coronary CTA, Comparison With Quantitative Coronary Angiography and Fractional Flow Reserve: A CREDENCE Trial Substudy, https://www.jacc.org/doi/10.1016/j.jcmg.2021.10.020). Cleerly's software uses "a series of validated convolutional neural network models (including VGG [Visual Geometry Group]-19 network, 3D U-Net, and VGG Network Variant) for image quality assessment, coronary segmentation and labeling, lumen wall evaluation and vessel contour determination, and plaque characterization." *Id.* The lumen and vessel wall contours identified constitute estimates of the boundary of the anatomic structure—i.e., the coronary artery. *Id.*

121. At least Claim 1 also requires determining a centerline of the anatomical structure. Upon information and belief, Cleerly's algorithm performs centerline extraction as a core processing step. For example, "[c]oronary centerlines are extracted by identifying possible coronary artery seed points and tracking and connecting individual seed points into a coronary tree." Ex. 43 (Griffin et al., https://www.jacc.org/doi/10.1016/j.jcmg.2021.10.020). Cleerly's centerline algorithm "was developed from 1,007,945 images, which comprised 23,068 vessels from 3,671 patients." *Id.* A separate validation study confirmed that Cleerly's deep learning algorithm "was applied to automate the process of coronary vessel detection, centerline extraction, and vessel wall and lumen segmentation." Ex. 44 (Coronary Artery Stenosis and High-Risk Plaque

Assessed With an Automated Deep Learning Algorithm, https://www.jacc.org/doi/10.1016/j.jacadv.2024.100861).

122. At least Claim 1 also requires extracting a plurality of frames from the received first image data, each successive frame in the plurality of frames defining a respective plane orthogonal to the centerline and intersecting the centerline at a respective successive point along a length of the centerline, and each frame formed from a plurality of pixels or voxels. Upon information and belief, Cleerly's segmentation process involves generating cross-sectional representations along the extracted centerline:

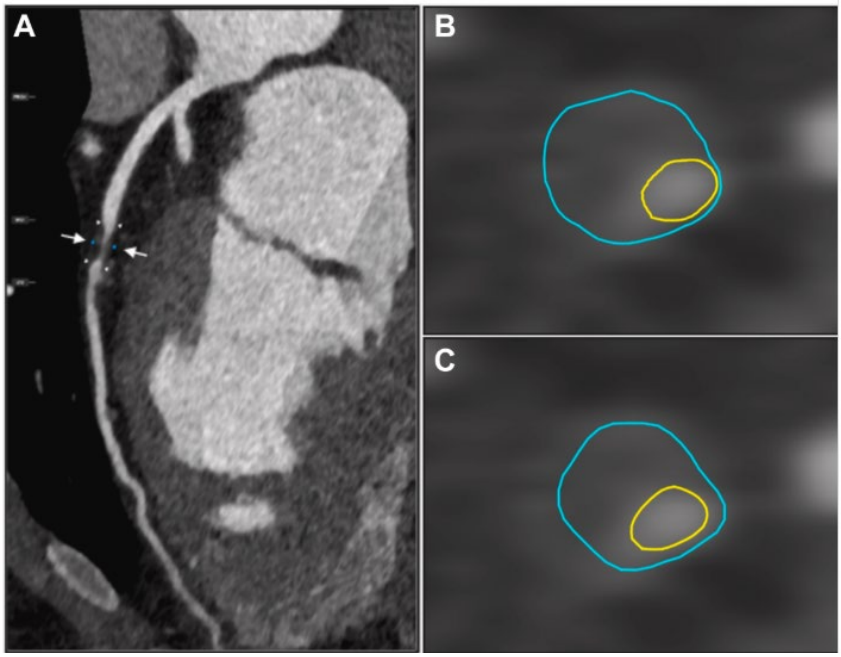


Figure 2 Comparison of Level 3 Expert Read and Deep Learning System Contouring of a Coronary Lesion

(A) Depicts a lesion in the mid-segment of the left anterior descending artery. (B) Shows a cross-section through the lesion at the level of the white arrows with manual plaque analysis contours performed by level 3 expert read overlayed, displaying a severe (70%-99%) stenosis. (C) Shows the same cross-section with automated plaque and contouring by the deep learning system, where stenosis was also reported as severe (70%-99%).

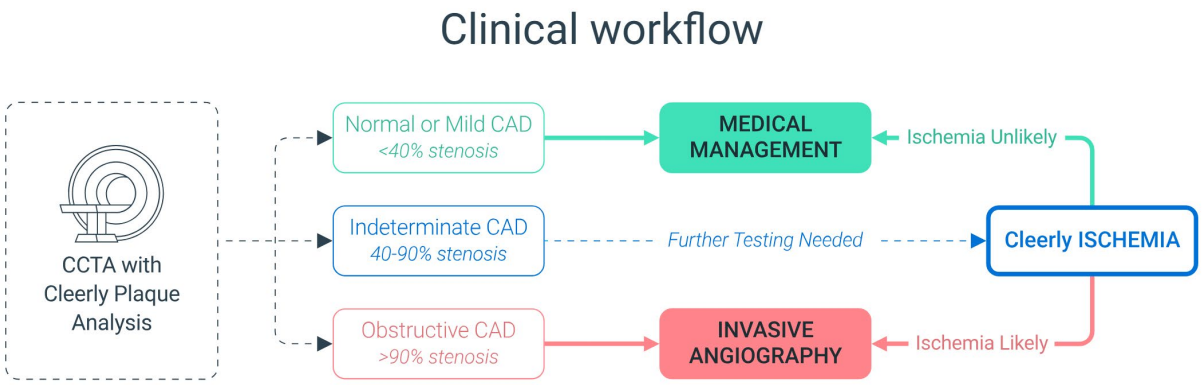
Ex. 44 (Coronary Artery Stenosis and High-Risk Plaque Assessed With an Automated Deep Learning Algorithm, https://www.jacc.org/doi/10.1016/j.jacadv.2024.100861)

123. Further, "[t]he lumen was segmented from the straightened multiplanar reformation of the tracked coronary artery," which constitutes extracting frames orthogonal to the

centerline along its length. Ex. 44 (Coronary Artery Stenosis and High-Risk Plaque Assessed With an Automated Deep Learning Algorithm, https://www.jacc.org/doi/10.1016/j.jacadv.2024.100861). As described in the relevant academic literature, the generation of a straightened multiplanar reformation (MPR) or curvilinear planar representation (CPR) is accomplished by extracting a set of planes—i.e., frames—along the centerline, orthogonal to the centerline, constituting a 3D volume. Ex. 45 (Deep Learning for Cardiac Image Segmentation: A Review, https://www.frontiersin.org/journals/cardiovascular-medicine/articles/10.3389/fcvm.2020.00025/full). Each extracted frame is necessarily formed from a plurality of pixels or voxels from the CCTA image data.

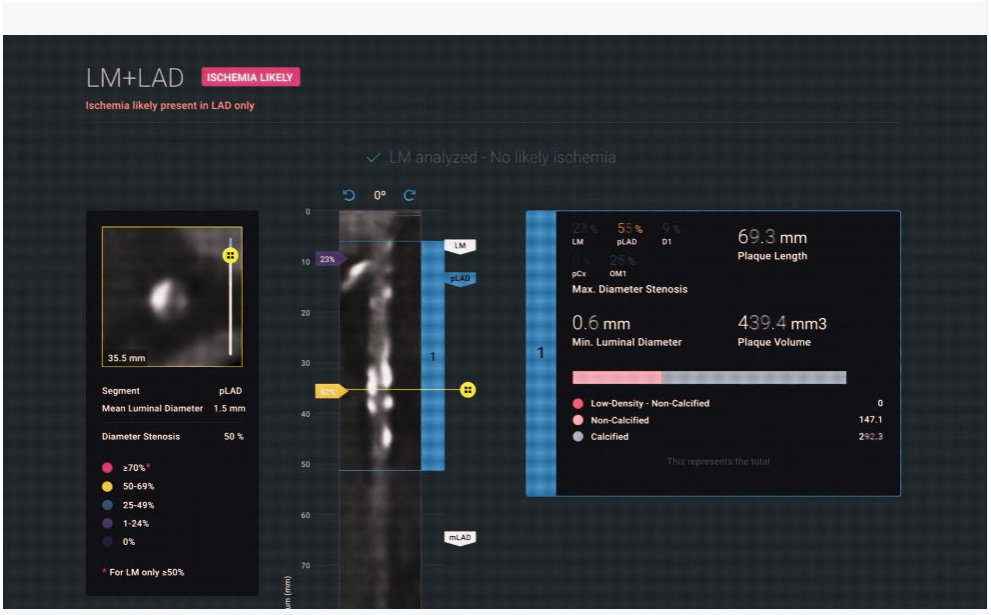
124. At least Claim 1 also requires determining, in each frame, a center point of the anatomic structure based on the intersection of the centerline and the respective plane. Upon information and belief, when Cleerly extracts the MPR or cross-sectional frames perpendicular to the centerline, the intersection of the centerline with each extracted plane inherently defines a center point in each frame. Ex. 43 (Griffin et al., https://www.jacc.org/doi/10.1016/j.jcmg.2021.10.020); Ex. 44 (Coronary Artery Stenosis and High-Risk Plaque Assessed With an Automated Deep Learning Algorithm, https://www.jacc.org/doi/10.1016/j.jacadv.2024.100861). This is a geometric consequence of extracting cross-sectional planes orthogonal to the centerline. Each plane intersects the centerline at a single point, which serves as the center point of the anatomic structure in that frame. The process of determining lumen boundaries and vessel wall contours in each cross-sectional frame necessarily relies on this center point as a reference. Ex. 43 (Griffin et al., https://www.jacc.org/doi/10.1016/j.jcmg.2021.10.020).

125. At least Claim 1 also requires generating, using a trained convolutional neural network (CNN), predictions of a plurality of locations of the boundary of the anatomic structure in the first image data based on the first image data, the determined center points of each of the frames, and the estimation of the boundary of the anatomic structure, wherein the trained CNN is configured to perform a regression of intensity values of the pixels or voxels in the plurality of frames along each of a plurality of radial angular directions out from each center point to generate the predictions of the plurality of locations of the boundary of the anatomic structure in the first image data. Upon information and belief, Cleerly uses trained convolutional neural networks—e.g., "VGG-19 network, 3D U-Net, and VGG Network Variant"—to perform "lumen wall evaluation and vessel contour determination." Ex. 43 (Griffin et al., https://www.jacc.org/doi/10.1016/j.jcmg.2021.10.020).

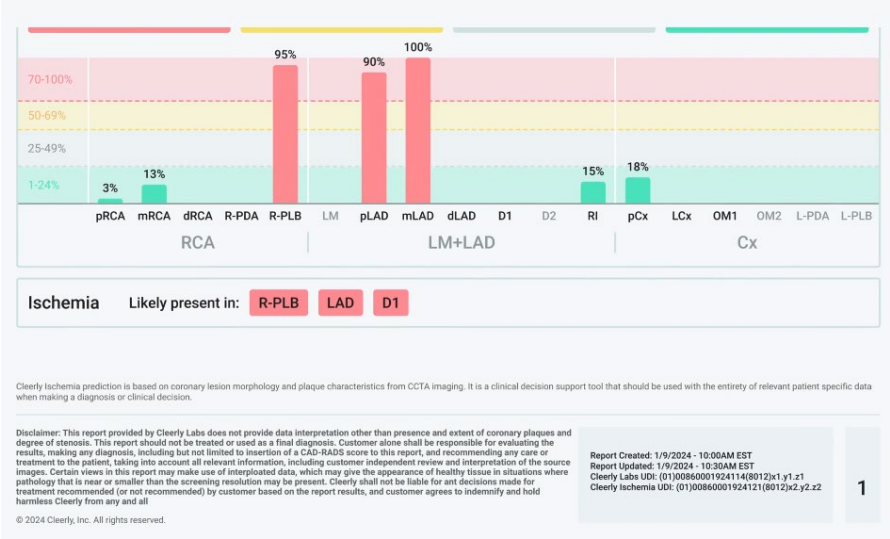


Ex. 26 (Cleerly Non-Invasive Ischemia Analysis, https://cleerlyhealth.com/ischemia-reinvented)

> Cleerly ISCHEMIA is a first-of-its-kind, FDA-cleared heart disease evaluation that uses 37 measures of heart health to determine likelihood of coronary artery ischemia at a per-vessel level. Cleerly ISCHEMIA uses machine learning and concise reporting to aid physicians in personalizing patient treatment, including the planning of interventional treatments such as stent placement.



Id.

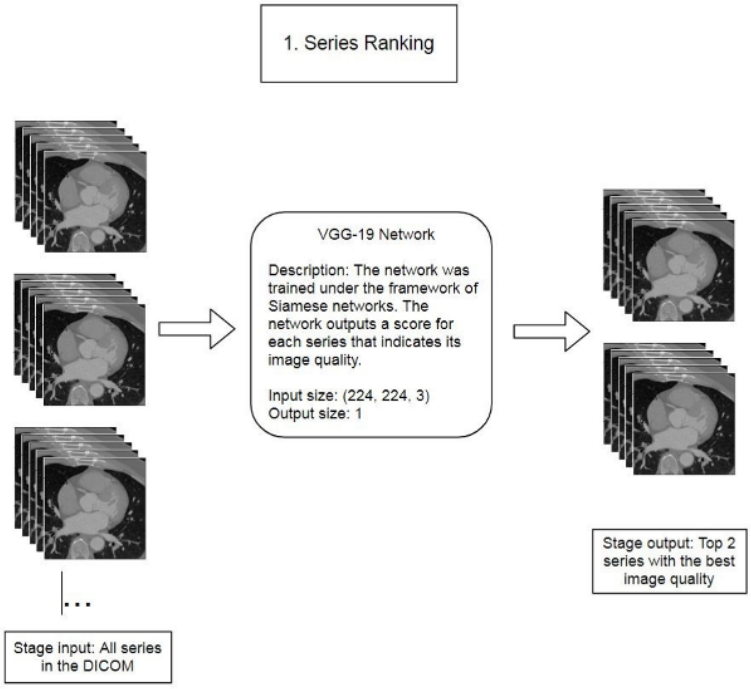


Id.

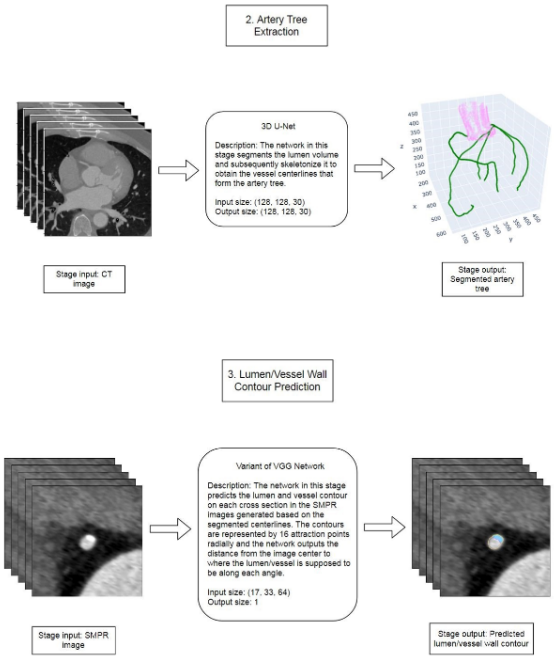
126. Upon information and belief, the CNN-based determination of vessel contours in cross-sectional frames extracted along the centerline—specifically, identifying the lumen boundary at multiple points around each cross-section—is consistent with generating predictions of boundary locations by analyzing intensity values radiating outward from the center point in multiple angular directions:

plaque is present; VGG Network Variant). Utilizing a normal proximal reference vessel cross-sectional slide, the start and the end of the lesion, and the cross-sectional slice that demonstrates the greatest absolute narrowing, % diameter stenosis severity is automatically calculated. The software determines the start and end of lesions and drops stenosis markers at the region of the highest stenosis. Within coronary artery lesions, plaque is quantified in a

Choi AD, et al. CT Evaluation of Coronary Artery Disease by AI: Appendix B (Ex. 49)



Id.



Id.

127. Upon information and belief, the validated method also employs these trained CNNs across the straightened MPR representation, where the lumen boundary is determined in cross-sectional slices, relying on the analysis of pixel intensity values from the center point outward to identify the vessel boundary—a process that is functionally equivalent to performing regression of intensity values along radial angular directions from the center point. *Id*; Ex. 44 (Coronary Artery Stenosis and High-Risk Plaque Assessed With an Automated Deep Learning Algorithm, https://www.jacc.org/doi/10.1016/j.jacadv.2024.100861); Ex. 46 (Nurmohamed et al., Development and Validation of a Quantitative Coronary CT Angiography Model, https://www.jacc.org/doi/10.1016/j.jcmg.2024.01.007).

128. Additional evidence of the Accused '813 Cleerly Products infringing Claims 1, 3, 4, 6-8, 10-13, 15, and 17-19 is included in the documents below, including representations Cleerly made in its FDA filings and details Cleerly disclosed about techniques it implements in the Accused '813 Cleerly Products in articles and appendices attached to the articles.

129. For example, an FDA submission dated September 22, 2020 includes representations by Cleerly that provide evidence of the Accused '813 Cleerly Products infringing one or more claims of the '813 Patent, including implementing "deep learning" and/or machine learning along with receiving images of anatomic structure, obtaining estimate of boundary conditions, and performing convolutional neural network (CNN):

Cleerly Labs is a web-based software application that is intended to be used by trained medical professionals as an interactive tool for viewing and analyzing cardiac computed tomography (CT) data for determining the presence and extent of coronary plaques (i.e., atherosclerosis) and stenosis in patients who underwent Coronary Computed Tomography Angiography (CCTA) for evaluation of CAD or suspected CAD. This software post processes CT images obtained using any Computed Tomography (CT) scanner. The software provides tools for the measurement and visualization of coronary arteries.

Cleerly 510(k) Summary, K202280, September 22, 2020 (Ex. 47)

4. Device Description

Cleerly Labs is a post-processing web-based software application that enables trained medical professionals to analyze 2D/3D coronary images acquired from Coronary Computed Tomography Angiography (CCTA) scans. The software is a post-processing tool that aids in determining treatment paths for patients suspected to have coronary artery disease (CAD).

Cleerly Labs utilizes machine learning and simple rule-based mathematical calculation components which are performed on the backend of the software. The software applies deep learning methodology to identify high quality images, segment and label coronary arteries, and segment lumen and vessel walls. 2D and 3D images are presented to the user for review and manual editing. This segmentation is designed to improve efficiency for the user, and help shorten tedious, time-consuming manual tasks.

Cleerly Labs provides a visualization of the Cleerly Labs analysis in the CORONARY Report. The CORONARY Report uses data previously acquired from the Cleerly Labs image analysis to generate a visually interactive and comprehensive report that details the atherosclerosis and stenosis findings of the patient. This report is not intended to be the final report (i.e., physician report) used in patient diagnosis and treatment. Cleerly Labs provides the ability to send the text report page of the CORONARY Report to the user's PACS system.

Id.

6. Software Functionality

In Cleerly Labs, users can edit the lumen and vessel walls of the suggested segmentation, and demarcate stenosis and stents, to more efficiently perform coronary analysis. Users are provided with navigation and editing/visualization tools to aid in image analysis. Plaque (i.e., atherosclerosis) and stenosis measurements are outputted based on the fully user-editable segmentation of the coronary artery. The user is also provided with the ability to indicate coronary anatomical findings.

Following the completion of study analysis, an interactive CORONARY Report is generated (the subject device of this submission). The CORONARY Report summarizes the analysis data from Cleerly Labs by reporting them as findings on atherosclerosis and stenosis, which may be used as supporting data in the evaluation of CAD. Components of the CORONARY Report include data visualization and reporting features. **Table 4** below compares the key features of the subject and predicate devices.

Id.

130. An additional FDA submission dated October 9, 2019 includes representations by Cleerly that also provide evidence of the Accused '813 Cleerly Products infringing one or more claims of the '813 Patent:

Device Description

Cleerly Labs is a post-processing web-based software application that enables trained medical professionals to analyze 2D/3D coronary images acquired from Computed Tomography (CT) angiographic scans. The software is a post-processing tool that aids in determining treatment paths for patients suspected to have coronary artery disease (CAD).

The output of the software includes visual images of coronary arteries, distance and volume measurements of the lumen wall, vessel wall, and plaque, remodeling index as well as stenosis diameter and area. These measurements are based on user segmentation.

Cleerly 510(k) Summary, K190868, October 9, 2019 (Ex. 48)

- A Usability test was conducted with U.S. board certified radiologists and technicians to ensure the clinical acceptability of the device.
- The machine learning algorithms were evaluated by comparing the output of the software to that of the ground truth using multiple ground truthers.

Id.

Visualization / Edit Tools	• Lumen Wall • Vessel Wall • Segment • Stenosis • Centerline • Plaque • Chronic Total Occlusion (CTO) • Stent • Exclude • Distance
2D Imaging	Yes
3D Imaging	Yes
Multiplanar Reformat (MPR)	Yes
Segmentation of region of interest	Manual and Semi-Automatic

Quantification	
Hounsfield Unit (HU)	Yes
Distance Measurements	• Vessel • Lesion • Length
Volumetric Measurements	• Total Vessel • Total Lumen • Non-Calcified Plaque (NCP) • Low-Density Non-Calcified Plaque (LD-NCP) • Calcified Plaque (CP) • Total Plaque
Remodeling Index	Yes
Stenosis	• % Area Stenosis • % Diameter Stenosis

Id.

131. Further, upon information and belief, the following publication provides evidence of specific techniques implemented by the Accused '813 Cleerly Products, including the use of CNN, determining stenosis, implementing machine learning, providing "scores," generating 3D

models, identifying dimensions, plaque quantification, and/or additional features demonstrating that the Accused '813 Cleerly Products infringe one or more claims of the '813 Patent:

Appendix B: Artificial Intelligence/Machine Learning Steps to CCTA Image Evaluation: The following figures present in graphical detail the stepwise use of artificial intelligence algorithms used for CCTA analysis.

This is an AI-aided approach (Cleerly Inc, New York, NY) that performs an automated analysis of CCTA using a series of validated convolutional neural network models (including VGG 19 network, 3D U-Net and VGG Network Variant) for image quality assessment, coronary segmentation and labeling, lumen wall evaluation and vessel contour determination and plaque characterization(19). No manual interaction is required from the reader. First, the AI-aided approach leverages 2 deep convolutional neural networks (VGG-19 Network and 3D U-Net) to produce a centerline along the length of the vessel, and then for lumen and outer vessel wall contouring. This approach is applied to multiple phases/series of the CCTA examination, if present, and enables phase-specific evaluation at the coronary segment vessel. The algorithm reviewed all series and determined the top 2 optimal series for further analysis including vessel and lumen segmentation, plaque, and stenosis quantification. The algorithm rank-orders all available phases for the segmentation of the arteries. It then uses the top two phases

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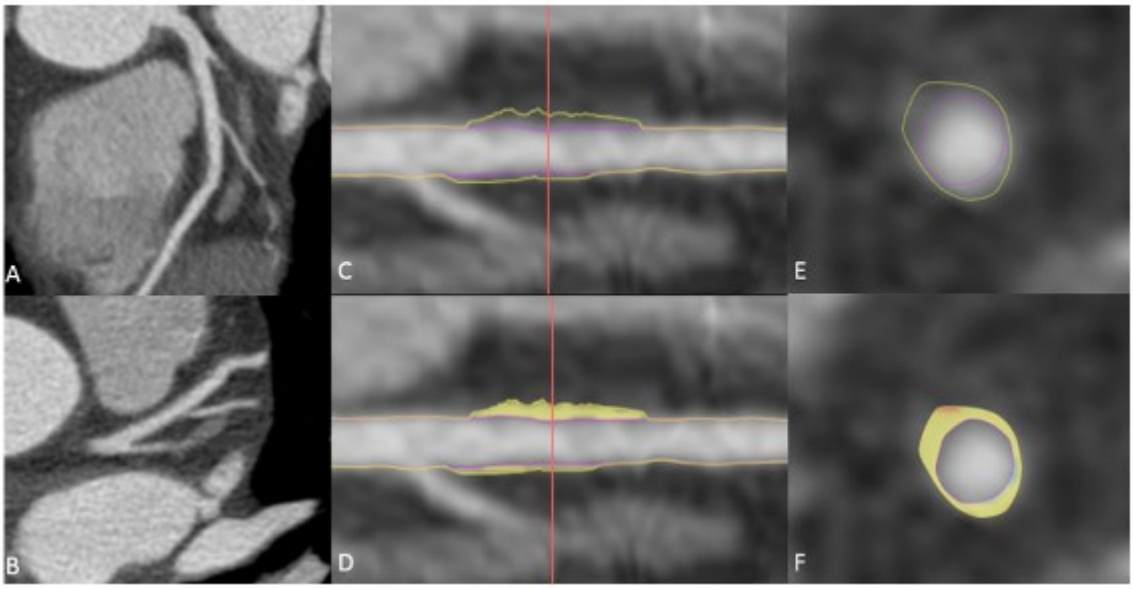
interactively on a per vessel basis, e.g., the right coronary artery (RCA) will be reconstructed from the phase which yields the highest RCA image quality, while the posterior descending artery (PDA) may come from the second phase if the PDA has a higher image quality on that phase. Once coronary artery segmentation is performed, an automated labeling is done to classify arteries by their location as well the proximal, mid and distal portions within a single vessel. The AI further allows for defining of coronary artery lesions (i.e., those areas where plaque is present; VGG Network Variant). Utilizing a normal proximal reference vessel cross-sectional slide, the start and the end of the lesion, and the cross-sectional slice that demonstrates the greatest absolute narrowing, % diameter stenosis severity is automatically calculated. The software determines the start and end of lesions and drops stenosis markers at the region of the highest stenosis. Within coronary artery lesions, plaque is quantified in a similar fashion, and further characterized as low-attenuation non-calcified plaque, non-calcified plaque and calcified plaque based upon Hounsfield unit (HU) densities of <30, -189 to 350, >350, respectively. Positive arterial remodeling was identified as a remodeling index ≥1.10 by diameter when compared to a proximal vessel reference. Vessel length, vessel volume, lumen volume, total plaque volume, calcified plaque volume, noncalcified plaque volume, low density noncalcified plaque volume, maximum diameter and area stenosis, and maximum remodeling index are calculated.

Id.

Supplement Figure 2: Contingency Tables of Level 3 Reader vs AI CAD-RADS Scores by CAD-RADS 0-3 and 4-5. These categories were chosen to represent a medical therapy (<70% stenosis) vs interventional (>70%) treatment threshold. On a per-vessel and per-patient basis, L3 and AI had 99.9% and 99.6% category agreement for these thresholds with weighted kappa values of 0.96 and 0.95 respectively.

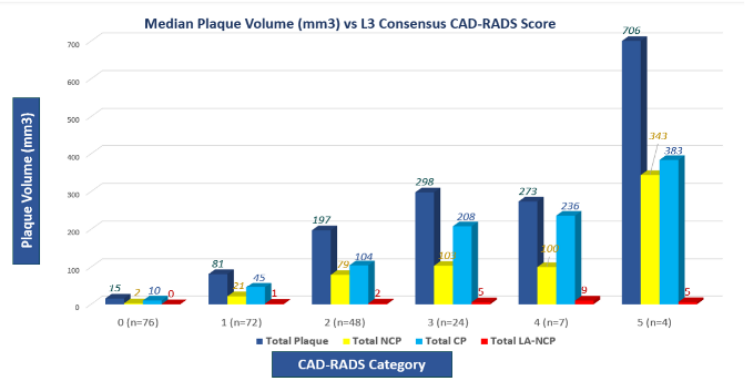
Choi AD, et al. CT Evaluation of Coronary Artery Disease by AI: Appendix A (Ex. 50)



Id.

Supplement Figure 3: Example case of discordance between AI and Level 3 Expert Consensus. The most common disagreement between expert consensus reads and AI reads was expert consensus CAD-RADS 0 and AI CAD-RADS 1. In this example of a 56-year-old male with dyspnea and a strong family history of CAD, the expert consensus read was a CAD-RADS 0 with no stenosis and no plaque (Panel A: Proximal and mid left anterior descending coronary artery curved multiplanar reformation [MPR]; Panel B: axial image of proximal and mid left anterior descending). The AI depicted 82 mm^3 of circumferential noncalcified plaque in the mid LAD with no coronary stenosis (Panel C: A straightened MPR depicting AI segmentation of the lumen boundary [purple line] and outer vessel wall [yellow line], Panel D: Same image as Panel C with a color overlay of noncalcified plaque (density >30 and < 350 HU), Panel E: A short axis MPR generated at the mid plaque level [red line] from image C again depicting lumen [purple] and vessel wall outer boundaries [yellow]; Panel F: Same as Panel E with color overlay of the noncalcified plaque [density >30 and < 350 HU]).

Id.



Supplemental Figure 4: **Median AI quantified plaque volume vs Level 3 Consensus by CAD-RADS Categorization**. Quantified plaque volume showed a broad range of values across CAD-RADS categories. NCP = Non-calcified plaque; CP = Calcified plaque; LA-NCP = Low attenuation non-calcified plaque

Id.

132. Further, upon information and belief, the functionality of the Accused '813 Cleerly Products is described in the paper titled "CT Evaluation by Artificial Intelligence for Atherosclerosis, Stenosis and Vascular Morphology (CLARIFY): A Multi-center, international study" (Ex. 51), which also provides additional evidence that the Accused '813 Cleerly Products infringe one or more claims of the '813 Patent:

Artificial Intelligence Segmentation and Plaque Quantification. CCTA studies were uploaded to and analyzed by FDA-cleared software Cleerly LABS (Cleerly, New York, New York).[17,18] The three sites contributing cases were not used for software development or validation. This study is an investigator initiated study and Cleerly had no role in the study design or performance. Cleerly performed AI-aided CCTA analyses for the study in a blinded manner, and provided statistical services as determined and requested by study investigators.

This is an AI-aided approach (**Central Illustration**) that performs automated analysis of CCTA using a series of validated convolutional neural network models (including VGG 19 network, 3D U-Net and VGG Network Variant) for image quality assessment, coronary segmentation and labeling, lumen wall evaluation and vessel contour determination and plaque characterization.[10,19] A full graphical representation of the algorithm with validation details is presented in Appendix B. First, the AI-aided approach leverages 2 deep convolutional neural networks to

Id.

quantification. The algorithm rank-orders all available phases for the segmentation of the arteries. It then uses the top two phases interactively on a per vessel basis, e.g., the right coronary artery (RCA) will be reconstructed from the phase which yields the highest RCA image quality, while the posterior descending artery (PDA) may come from the second phase if the PDA has a higher image quality on that phase. Once coronary artery segmentation is performed, an automated labeling is done to classify arteries by their location as well the proximal, mid and distal portions within a single vessel. The AI further allows for defining of coronary artery lesions (i.e., those areas where plaque is present). Utilizing a normal proximal reference vessel cross-sectional slide, the start and the end of the lesion, and the cross-sectional slice that demonstrates the greatest absolute narrowing, % diameter stenosis severity is auto-

Id.

matically calculated. The software determines the start and end of lesions and drops stenosis markers at the region of the highest stenosis. Within coronary artery lesions, plaque is quantified in a similar fashion, and further characterized as low-attenuation non-calcified plaque, non-calcified plaque and calcified plaque based upon Hounsfield unit (HU) densities of <30, −189 to 350, >350, respectively. Positive arterial remodeling was identified as a remodeling index ≥1.10 by diameter when compared to a proximal vessel reference. We used a coronary ar-

Id.

L3 readers determined maximum diameter stenosis was compared with AI stenosis on a per-patient and per-vessel basis. Correlation and numeric agreement were assessed. The Pearson correlation coefficient was used to evaluate correlation, linear regression plots were generated for visualization of the relationship. Bland-Altman plots with limits of agreement was performed. Diagnostic performance of AI vs L3 was assessed through diagnostic accuracy, sensitivity, specificity, positive and negative predictive values at both >50% and >70% stenosis thresholds on per vessel and per patient basis.

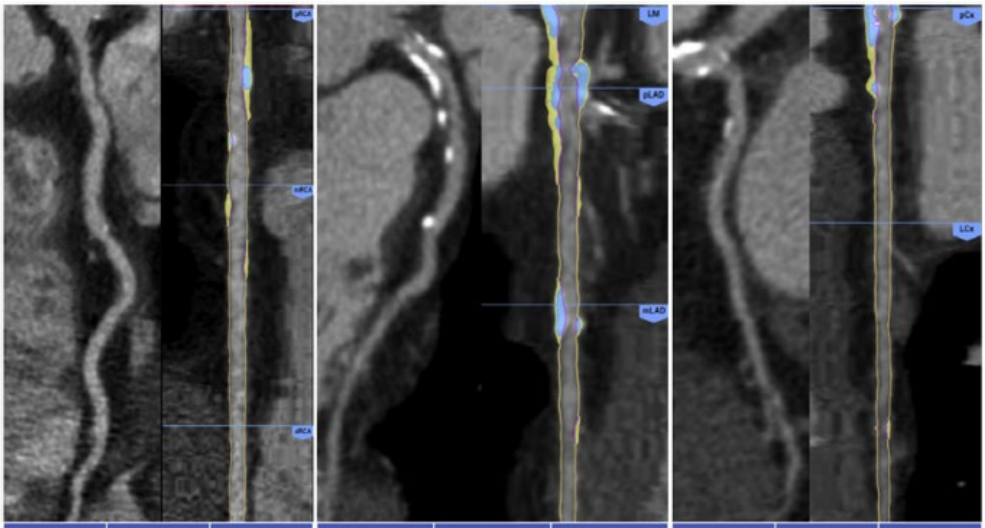
Id.

Readers determined presence of two high risk plaque features—low attenuation plaque <30 Hounsfield units (HU) and positive arterial remodeling with a remodeling index ≥1.10 by diameter—with this analysis compared with AI on per vessel and per patient basis. This binary outcome was compared by calculating the percent agreement and kappa statistic.

Id.

CAD-RADS Categorization. Fig. 1 depicts consensus reads versus AI results. Overall, 182/232 (78.0%) had CAD-RADS categorical agreement, 228/232(98.3%) agreed within one category. The most frequent disagreement occurred with expert consensus CAD-RADS 0 and AI CAD-RADS 1 (n = 29 12.5% per patient, n = 161 17.4% per vessel). To further evaluate L3 consensus vs AI for a collated mild-moderate versus severe stenosis categories, at a threshold for potential interventional treatment (>70% stenosis), we evaluated CAD-RADS 0–3 and CAD-RADS 4–5 to assess accuracy and found only 1 case of discrepancy on either a per-

Id.



	Consensus	AI
RCA	26%	35%

	Consensus	AI
Left Main	55%	60%
LAD	53%	47%

	Consensus	AI
Circumflex	24%	34%

Id.

Fig. 2. Example Case of Consensus Between Artificial Intelligence and Level 3. Example of a study depicting excellent agreement between maximal percent diameter stenosis in a 53-year-old make with exertional chest pain. On the left readers using a curved multiplanar reformat (cMPR) of the RCA determined a consensus stenosis of 26%, the straightened MPR to its right with colored plaque overlay (in blue and yellow) generated by AI found 35% maximal stenosis. In the middle the cMPR used by readers determined 55% stenosis of the left main and 53% of the LAD, AI to its right with colored plaque overlay (in blue and yellow) by AI found 53 and 47% respectively. On the right the cMPR used by readers determined 24% stenosis of the left circumflex, AI with colored plaque overlay (in blue and yellow) by AI determined 34%. (For interpretation of the references to color in this figure legend, the reader is referred to the Web version of this article.)

Machine Learning Applied to CCTA. Recent studies have begun to evaluate individual aspects of AI-enabled plaque quantification, though few of these solutions are currently available clinically. Zreik et al. used a multitask recurrent convolutional neural network in n = 166 for automatic characterization of plaque.[38] They achieved a linearly weighted kappa of 0.68, 0.66 and 0.67 at the segment, artery and patient-level for the binary presence or absence of non-calcified, mixed and calcified plaque. Kang et al. used a support vector machine (SVM) learning algorithms in a small number of datasets (n = 42) for detection of plaque for lesions a simplistic severity of ≥25% in comparison to experienced expert consensus readers and reported accuracy of 94%.[39]

Id.

133. The foregoing features and capabilities of each of the Accused '813 Cleerly Products description and/or demonstration thereof, including in advertising, reflect Cleerly's direct infringement by satisfying every element of at least Claims 1, 3, 4, 6-8, 10-13, 15, and 17-19 of the '813 Patent under 35 U.S.C. § 271(a).

134. Upon information and belief, Cleerly has induced infringement, and continues to induce infringement, of one or more Claims 1, 3, 4, 6-8, 10-13, 15, and 17-19 of the '813 Patent

by actively and knowingly inducing others, including health care providers and hospitals in the Eastern District of Texas and throughout the United States, to directly infringe one or more claims of the '813 Patent through the use of Cleerly's products and services. For example, Cleerly instructs hospital employees and doctors, and induces patients through its website, via generating tutorial videos for training purposes, training hospital employees, conducting webinars, conducting demos at events, and/or producing instructional videos to induce them to directly infringe one or more claims of the '813 Patent through the use of the Accused '813 Cleerly Products. *See* https://www.youtube.com/@cleerlyhealth/videos (Ex. 42); https://cleerlyhealth.com/clinical-publications; https://cleerlyhealth.com/blog; https://cleerlyhealth.com/webinars; https://cleerlyhealth.com/events.

135. Upon information and belief, Cleerly has contributed to the infringement of one or more of Claims 1, 3, 4, 6-8, 10-13, 15, and 17-19 of the '813 Patent by providing products and services that constitute material parts of the claimed inventions, knowing the same to be especially made or adapted for use in an infringing manner. For example, the Accused '813 Cleerly Products include at least one component to generate images and implement CNN to be used in conjunction with the Cleerly Platform to perform CAD detection. This is a component of a patented machine, manufacture, or combination, or an apparatus for use in practicing a patented process. Furthermore, such component is a material part of the invention, and upon information and belief, is not a staple article or commodity of commerce suitable for substantial non-infringing use. Thus, Cleerly is liable for infringement of the '813 Patent pursuant to 35 U.S.C. § 271(c).

136. Upon information and belief, Cleerly has been on notice of the '813 Patent at least since its issuance, and Cleerly's infringement of the '813 Patent has been and continues to be willful. For example, Cleerly, through its founder, Dr. James K. Min, had actual knowledge of

Heartflow's patent portfolio through Dr. Min's role as a Heartflow consultant from 2012 to 2017, his execution of an NDA and Consulting Agreement with Heartflow, and his role as lead investigator on Heartflow's DeFACTO study. Dr. Min incorporated Cleerly on July 19, 2016 while still subject to the Consulting Agreement and its confidentiality, non-compete, and invention assignment obligations. Cleerly further acquired actual knowledge of Heartflow's patents through its hiring of Brent Ness, Heartflow's former Chief Commercial Officer, who was bound by confidentiality obligations under the Ness Agreement and Separation Agreement. Cleerly has knowledge about the '813 Patent based on Cleerly citing the '813 Patent repeatedly in its own patents as seen below:

Heartflow's Patent	**Cleerly Patent Citing Heartflow's Patent**
US11288813B2	US11501436B2 US11642092B1 US11690586B2 US11861833B2 US11922627B2 US12144669B2 US12380560B2 US12440180B2

137. By the time of trial, Cleerly will thus have known and intended (since receiving such notice), that its continued actions would actively induce and contribute to actual infringement of one or more Claims 1, 3, 4, 6-8, 10-13, 15, and 17-19 of the '813 Patent.

138. Despite this actual knowledge of Heartflow's patents, Cleerly deliberately chose to develop and commercialize infringing products rather than seek a license of those patents.

139. Cleerly undertook and continues its infringing actions despite an objectively high likelihood that such activities infringed the '813 Patent, which has been duly issued by the USPTO and is presumed valid. For example, Cleerly has been aware of an objectively high likelihood that

its actions constituted, and continue to constitute, infringement of the '813 Patent based on Dr. Min's actual knowledge and Cleerly's knowledge as shown on Cleerly's own patents, and that the '813 Patent is valid. On information and belief, Cleerly cannot reasonably, subjectively believe that their actions do not constitute infringement of the '813 Patent, nor could it reasonably, subjectively believe that the patent is invalid. Despite that knowledge and subjective belief, and the objectively high likelihood that its actions constitute infringement, Cleerly has continued its infringing activities. As such, Cleerly willfully infringes the '813 Patent.

140. Heartflow has been damaged by Cleerly's infringement of the '813 Patent and is entitled to recover damages adequate to compensate for such infringement pursuant to 35 U.S.C. § 284.

COUNT 2 – CLEERLY'S INFRINGEMENT OF U.S. PATENT NO. 11,382,569

141. Heartflow incorporates all preceding paragraphs by reference.

142. U.S. Patent No. 11,382,569 (the "'569 Patent") was duly issued on July 12, 2022, and is titled "Systems and methods for estimating blood flow characteristics from vessel geometry and physiology." A copy of the '569 Patent is attached as Exhibit 8.

143. Heartflow is the owner by assignment of the '569 Patent and possesses all rights under the '569 Patent, including the exclusive right to recover for past and future infringement.

144. The '569 Patent is directed to systems and methods for estimating patient-specific blood flow characteristics from vessel geometry and physiology. For example, the '569 Patent discloses a method for determining individual-specific blood flow characteristics comprising: acquiring, by a processor, for each of a plurality of individuals, an individual-specific geometric model of at least part of a vascular system of each individual and values of a blood flow characteristic at one or more points of each individual's vascular system; training, by the processor,

a machine learning algorithm using individual-specific anatomic data derived from one or more points of each individual-specific geometric model and the values of the blood flow characteristic at the one or more points of each individual's vascular system, wherein the training of the machine learning algorithm generates learned associations by relating features identified from each individual's individual-specific anatomic data and the blood flow characteristic derived from each individual's individual-specific anatomic data at the one or more points of each individual-specific geometric model, and the individual-specific anatomical data includes a vascular cross section area, a diseased length, and one or more boundary conditions of the individual-specific geometric model at the one or more points; acquiring, by the processor, for a patient different from the plurality of individuals, one or more images of patient-specific anatomic data of at least part of the patient's vascular system, wherein the patient-specific anatomic data includes data corresponding to a lesion of interest in the patient's vascular system; generating, by the processor, a geometric model of an image region comprising the lesion of interest in the patient's vascular system, the image region corresponding to features of the patient's anatomy predictive of the blood flow characteristic; and executing, by the processor, the trained machine learning algorithm for at least a point of the geometric model of the image region of the patient to non-invasively determine values of the blood flow characteristic at one or more points of the geometric model of the patient's vascular system, using the learned associations of features related between the individual-specific anatomic data and the blood flow characteristic.

145. The '569 Patent explains that, at the time of its priority date, a functional assessment of arterial capacity was important for treatment planning to address patient needs, and studies had demonstrated that hemodynamic characteristics, such as Fractional Flow Reserve (FFR), were important indicators to determine the optimal treatment for a patient with arterial disease.

However, conventional assessments of these hemodynamic characteristics used invasive catheterizations to directly measure blood flow characteristics, such as pressure and flow velocity, which presented severe risks to the patient and significant costs to the health care system. '569 Patent at 1:25-36. To address these risks and costs, a new generation of noninvasive tests were developed that used patient imaging, such as computed tomography (CT), to determine a patient-specific geometric model of the blood vessels, and this model was used computationally to simulate the blood flow using computational fluid dynamics (CFD) with appropriate physiological boundary conditions and parameters. *Id.* at 1:37-44.

146. The '569 Patent solved these problems by providing new approaches for performing rapid, noninvasive estimations of blood flow characteristics that are computationally inexpensive, incorporating machine learning techniques to determine noninvasive estimations of blood flow characteristics without the need for CFD method. *Id.* at 1:56-2:6. More specifically, the claimed invention includes a processor that acquires, for each of a plurality of individuals, an individual-specific geometric model of at least part of a vascular system and values of a blood flow characteristic at one or more points of each individual's vascular system.

147. The processor then trains a machine learning algorithm using individual-specific anatomic data—including a vascular cross section area, a diseased length, and one or more boundary conditions—derived from points of each individual-specific geometric model and the values of the blood flow characteristic, generating learned associations by relating identified features to the blood flow characteristic. As such, the claimed invention can acquire, for a patient different from the training individuals, one or more images of patient-specific anatomic data corresponding to a lesion of interest in the patient's vascular system, and generate a geometric

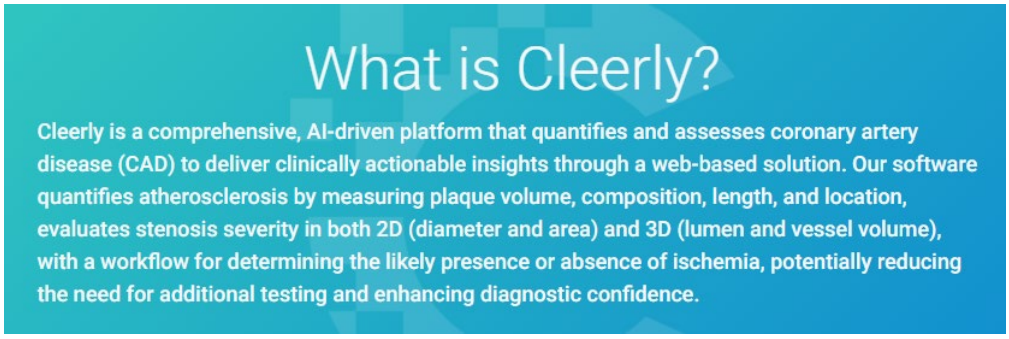
model of an image region comprising the lesion of interest that corresponds to features of the patient's anatomy predictive of the blood flow characteristic.

148. Accordingly, the trained machine learning algorithm is executed for at least a point of the geometric model of the image region of the patient to non-invasively determine values of the blood flow characteristic using the learned associations of features related between the individual-specific anatomic data and the blood flow characteristic. Therefore, a method for determining individual-specific blood flow characteristics with improved speed, reduced computational burden, and without the severe risks of invasive measurement techniques is achieved.

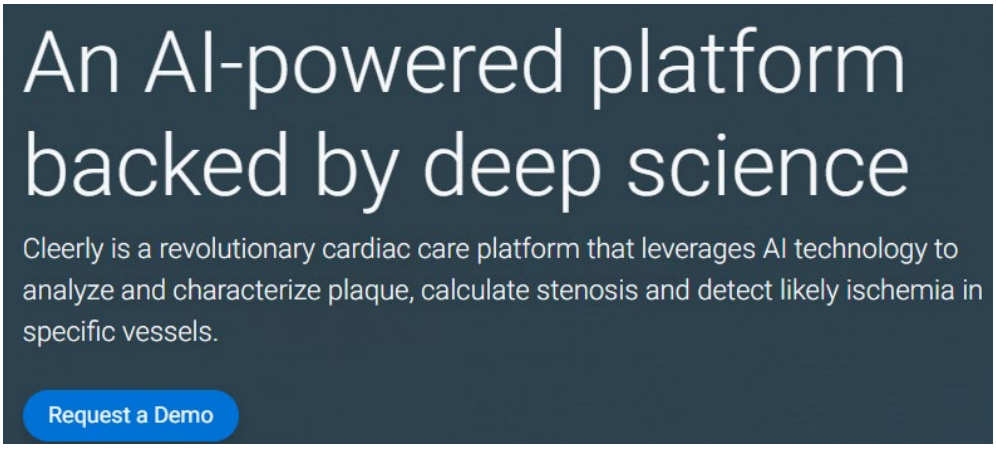
149. Evidence that the '569 Patent is valid and is directed to novel and inventive technology is discussed above in at least paragraphs 17-41 and 96-103 and incorporated by reference. Further, the '569 Patent has been recognized as a foundational patent as shown by the fact that it has been cited in over 98 additional patents, including patents filed by Cathworks Ltd., Cleerly, Elucid Bioimaging Inc., and Koninklijke Philips N.V.

150. Upon information and belief, Cleerly has directly infringed, and continues to directly infringe, one or more claims of the '569 Patent in this District and elsewhere in Texas, including at least Claims 1, 2, 4-9, 11-13, and 15-17 literally and/or under the doctrine of equivalents, making, using, selling, offering to sell, and/or importing into the United States products and services that practice the inventions claimed therein, including, but not limited to, Cleerly Plaque Analysis and Cleerly ISCHEMIA (collectively, "the Accused '569 Cleerly Products"). For example, Cleerly provides a "comprehensive, AI-driven platform that quantifies and assesses coronary artery disease (CAD)" that "quantifies atherosclerosis by measuring plaque volume, composition, length, and location, evaluates stenosis severity in both 2D (diameter and

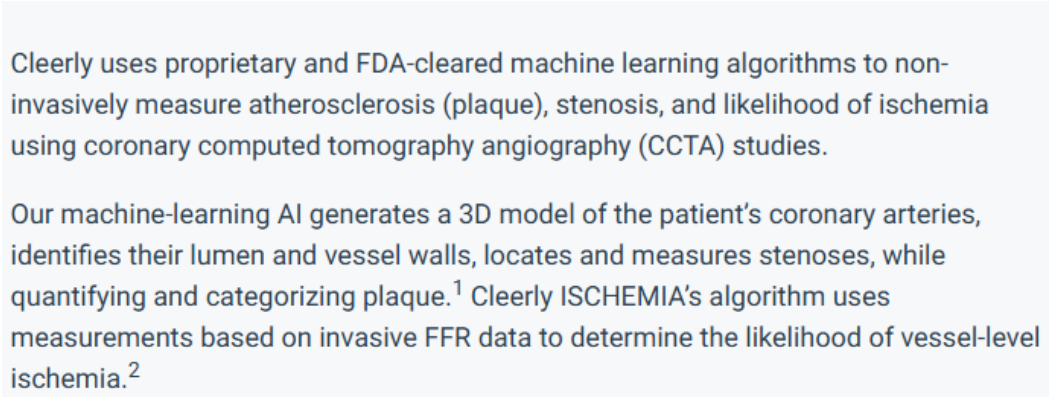
area) and 3D (lumen and vessel volume), with a workflow for determining the likely presence or absence of ischemia." https://cleerlyhealth.com/ (Ex. 29).



https://cleerlyhealth.com/ (Ex. 29)



https://cleerlyhealth.com/what-is-cleerly (Ex. 41)



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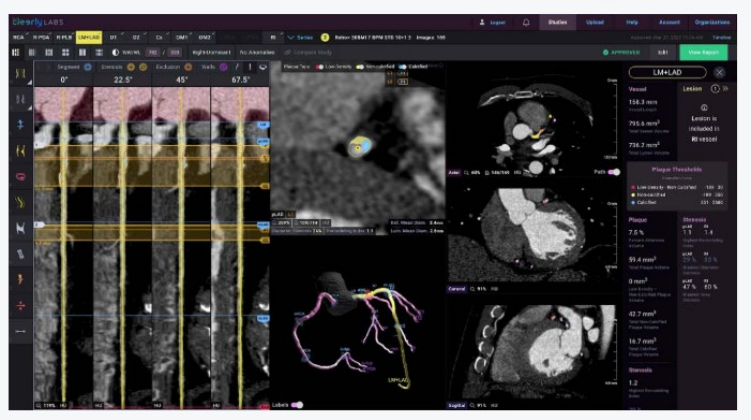

https://cleerlyhealth.com/what-is-cleerly (Ex. 41)

https://cleerlyhealth.com/what-is-cleerly (Ex. 41)

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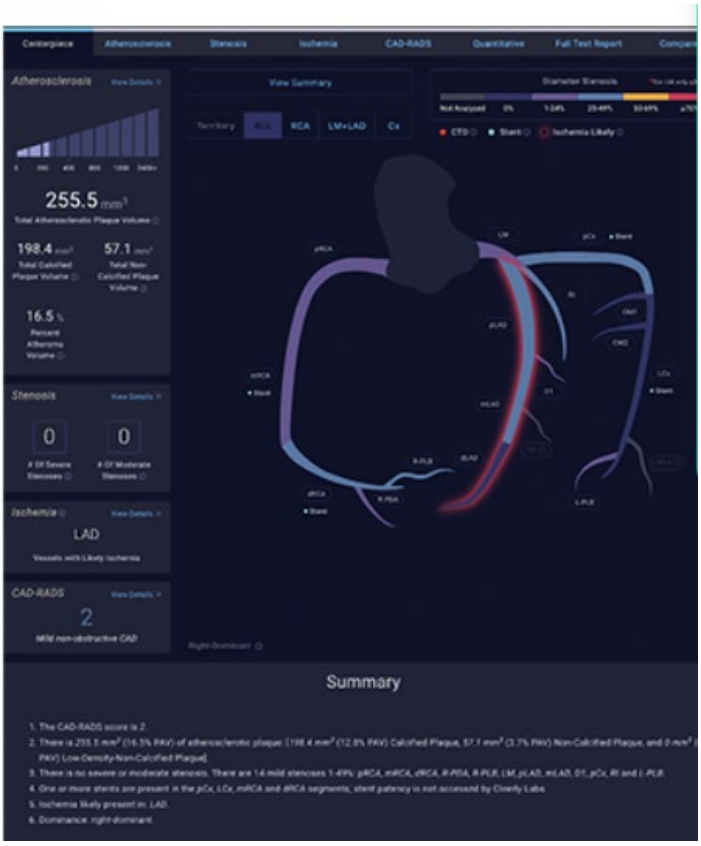
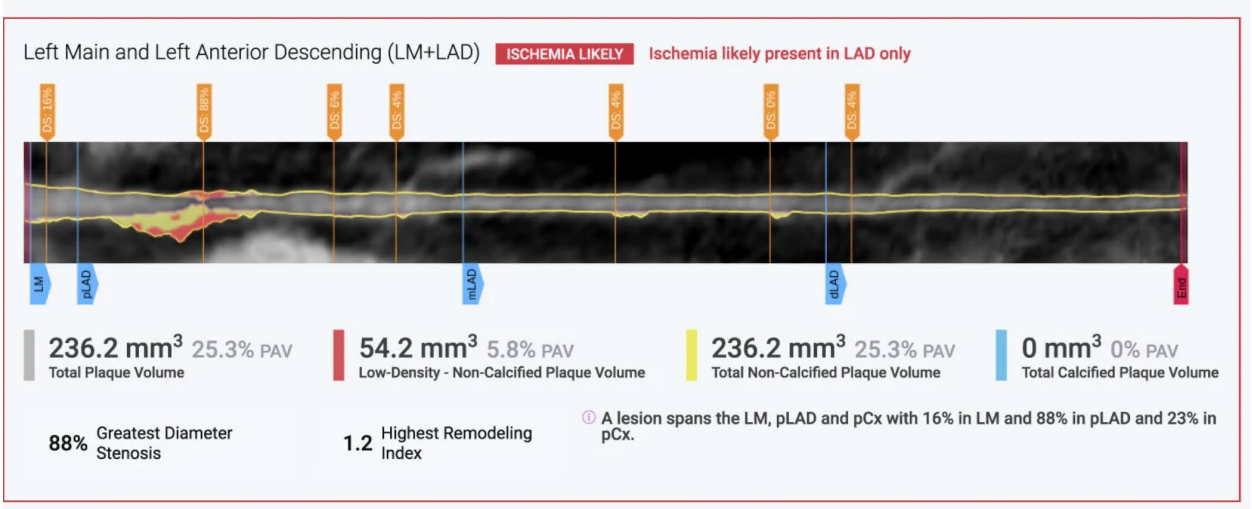
https://cleerlyhealth.com/what-is-cleerly (Ex. 41)



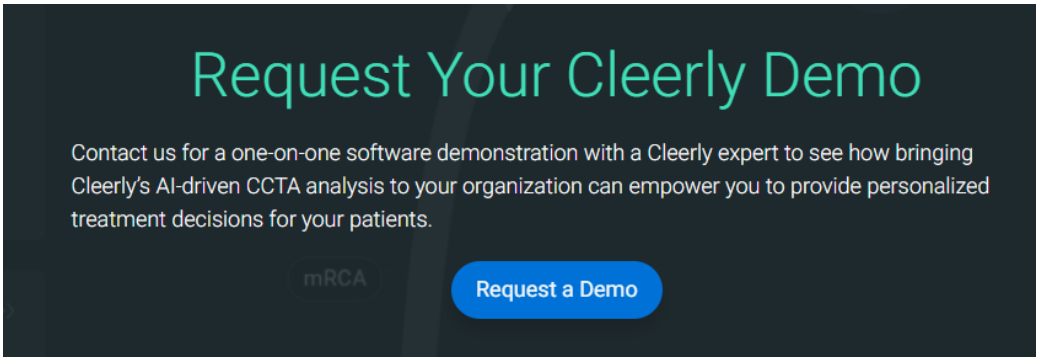
https://cleerlyhealth.com/what-is-cleerly (Ex. 41)



https://cleerlyhealth.com/patient-education (Ex. 35)

151. Heartflow reserves the right to discover and pursue any additional infringing products and services that incorporate infringing functionalities. For the avoidance of doubt, the Accused '569 Cleerly Products are identified to describe Cleerly's infringement and in no way limit the discovery and infringement allegations against Cleerly concerning other products that incorporate the same or reasonably similar functionalities.

152. Upon information and belief, Cleerly directly infringes by performing one or more method claims in the United States when, for example, performing testing, including "usability tests" as confirmed in FDA submissions, generating tutorial videos for training purposes, training hospital employees, conducting webinars, conducting demos at events, and/or producing instructional videos showing how the Accused '569 Cleerly Products operate. https://www.youtube.com/@cleerlyhealth/videos (Ex. 42); https://cleerlyhealth.com/clinical-publications; https://cleerlyhealth.com/blog; https://cleerlyhealth.com/webinars; https://cleerlyhealth.com/events.



153. Each of the Accused '569 Cleerly Products, either alone or in combination with each other, perform a method for determining individual-specific blood flow characteristics.

154. At least Claim 1 requires acquiring, by a processor, for each of a plurality of individuals, an individual-specific geometric model of at least part of a vascular system of each individual and values of a blood flow characteristic at one or more points of each individual's

vascular system. Cleerly described their method: "Coronary CTA scans from both studies were analyzed using the previously described AI-QCT algorithm. This Food and Drug Administration (FDA)-cleared software uses a series of validated convolutional neural networks (3-dimensional U-Net and Visual Geometry Group [VGG] network variants) for image-quality assessment, coronary segmentation and labeling, lumen-wall evaluation and vessel contour determination, and plaque characterization." Nurmohamed et al., "Development and Validation" (JACC Cardiovasc. Imaging) (Ex. 46). Combined the geometric models from CCTA images with FFR blood flow data: "Using these parameters, a model predicting ischemia was developed in the 307 patients in the derivation cohort of CREDENCE to predict a binary presence of ischemia defined as an invasive FFR #0.80 on a per-vessel basis. The model was developed using only the test results and invasive FFR measurements from the CREDENCE derivation cohort. *Id.*

155. Cleerly's technology is described as being "based on over 10 million images from over 40,000 patients gathered over a 15-year-period in landmark, multi-center clinical trials." Ex. 41 (What is Cleerly, https://cleerlyhealth.com/what-is-cleerly); (TCT 2025 Late-Breaking Science, https://cleerlyhealth.com/press/tct-2025-late-breaking-science). Its machine learning algorithms used data from large-scale coronary imaging studies, including millions of annotated lab images. Ex. 52 (Cleerly Plaque Analysis, https://cleerlyhealth.com/plaque-analysis) Cleerly's AI-QCT ISCHEMIA model was specifically "tested on patients with suspected stable coronary artery disease who underwent various heart imaging tests," with invasive FFR serving as the gold standard for blood flow characteristic values. (Cleerly Secures CPT® Category I Code for AI-QCT Advanced Plaque Analyses, https://cleerlyhealth.com/press/cpt-1-code-plaque-analyses); (Cleerly Receives FDA Breakthrough Device Designation,

https://cleerlyhealth.com/press/breakthrough-device-designation-heart-disease-risk-staging-system).

156. At least Claim 1 also requires training, by the processor, a machine learning algorithm using individual-specific anatomic data derived from one or more points of each individual-specific geometric model and the values of the blood flow characteristic, where the anatomic data includes a vascular cross section area, a diseased length, and one or more boundary conditions. Upon information and belief, Cleerly's software "utilizes a series of validated convolutional neural networks (3D U-Net and VGG network variants) for image quality assessment, coronary segmentation and labelling, lumen wall evaluation and vessel contour determination, and plaque characterization." Ex. 53 (Bär et al., Prognostic value of a novel artificial intelligence-based coronary computed tomography angiography-derived ischemia algorithm for patients with suspected coronary artery disease, https://pmc.ncbi.nlm.nih.gov/articles/PMC11057943/). Upon information and belief, the Cleerly ISCHEMIA algorithm employs "a random forest machine-learned algorithm" that "determines the probability of abnormal invasive fractional flow reserve (FFR) using 38 CCTA-derived quantitative variables from Cleerly LABS." *Id.* These parameters encompass quantitative measures of atherosclerosis, stenosis, and significant vascular morphology—including stenosis diameter percentages, plaque volumes, lumen volumes, and vessel dimensions—derived from patients' CCTA images. *Id.*; (Cleerly Launches Cleerly ISCHEMIA Solution for Heart Disease Analysis, https://cleerlyhealth.com/press/cleerly-launches-ischemia-heart-disease-analysis). The plaque characteristics analyzed include maximum stenosis diameter percentage, total calcified plaque, total non-calcified plaque, low-density plaque, lumen volume, and total plaque—characteristics that correspond to measurements of vascular cross-sectional area, diseased length,

and boundary conditions as recited in Claim 1. Ex. 53 (Bär et al., https://pmc.ncbi.nlm.nih.gov/articles/PMC11057943/). Specifically, Cleerly states their product uses a percent area stenosis, which requires a cross-sectional area, a maximum lesion length, and various vessel and plaque volumes, all of which require defining a boundary separating plaque, lumen, vessel wall, and other tissue. (Nurmohamed, et al., 2024).

157. At least Claim 1 also requires that the training of the machine learning algorithm generates learned associations by relating features identified from each individual's individual-specific anatomic data and the blood flow characteristic. Upon information and belief, the Cleerly ISCHEMIA model was trained to predict invasive FFR ≤ 0.80 on a per-vessel basis by relating quantitative atherosclerotic and vascular morphology features to invasive FFR values obtained from the CREDENCE and PACIFIC trial cohorts. Ex. 53 (Bär et al., https://pmc.ncbi.nlm.nih.gov/articles/PMC11057943/) The model generates a binary indication—the Cleerly ISCHEMIA Index (CII)—of likely ischemia (equivalent to invasive FFR ≤ 0.80 vs. > 0.80), which is an example of a learned association between anatomic features and blood flow characteristics. *Id.*; Ex. 55 (FDA 510(k) Summary for Cleerly ISCHEMIA (K231335), https://www.accessdata.fda.gov/cdrh_docs/pdf23/K231335.pdf).

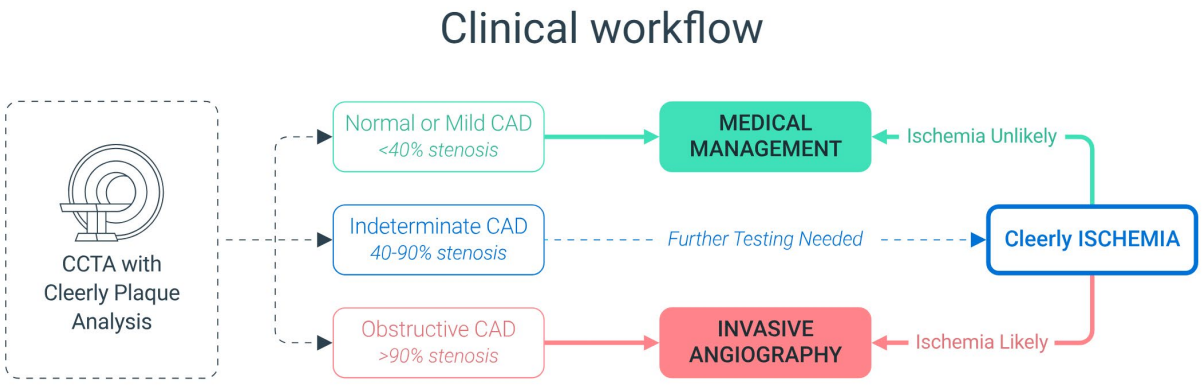
158. At least Claim 1 also requires acquiring, by the processor, for a patient different from the plurality of individuals, one or more images of patient-specific anatomic data, wherein the patient-specific anatomic data includes data corresponding to a lesion of interest in the patient's vascular system. As listed on its website, Cleerly acquires and analyzes a patient's CCTA images, which are noninvasive imaging studies of the patient's coronary arteries. Ex. 41 (What is Cleerly, https://cleerlyhealth.com/what-is-cleerly); Ex. 56 (Cleerly Presents Late-Breaking Research on AI-Enabled Quantitative CT Coronary Assessment, https://cleerlyhealth.com/press/research-on-

ai-enabled-quantitative-ct-coronary-assessment). Cleerly identifies, quantifies, and characterizes plaque—including the location and type of lesions—within the patient's coronary vessels. Ex. 57 (Cleerly Atherosclerosis, Stenosis and Ischemia Analysis, https://cleerlyhealth.com/diagnosing-cad). The patients being analyzed are necessarily different from the plurality of individuals whose data was used to train the algorithm over the prior 15-year period. (TCT 2025 Late-Breaking Science, https://cleerlyhealth.com/press/tct-2025-late-breaking-science).

159. At least Claim 1 also requires generating, by the processor, a geometric model of an image region comprising the lesion of interest in the patient's vascular system, the image region corresponding to features of the patient's anatomy predictive of the blood flow characteristic. Upon information and belief, Cleerly's "machine-learning AI generates a 3D model of the patient's coronary arteries, identifies their lumen and vessel walls, locates and measures stenoses, while quantifying and categorizing plaque." Ex. 41 (What is Cleerly, https://cleerlyhealth.com/what-is-cleerly). This 3D model encompasses the image regions containing lesions, and the plaque and stenosis measurements derived from the model are the very features used to predict the blood flow characteristic (FFR/ischemia). Ex. 54 (Cleerly Launches Cleerly ISCHEMIA Solution for Heart Disease Analysis, https://cleerlyhealth.com/press/cleerly-launches-ischemia-heart-disease-analysis); Ex. 53 (Bär et al., https://pmc.ncbi.nlm.nih.gov/articles/PMC11057943/). Cleerly's updated reports also now include "detailed information about each lesion" and "lesion-specific data" in the provider report. Ex. 41 (What is Cleerly, https://cleerlyhealth.com/what-is-cleerly).

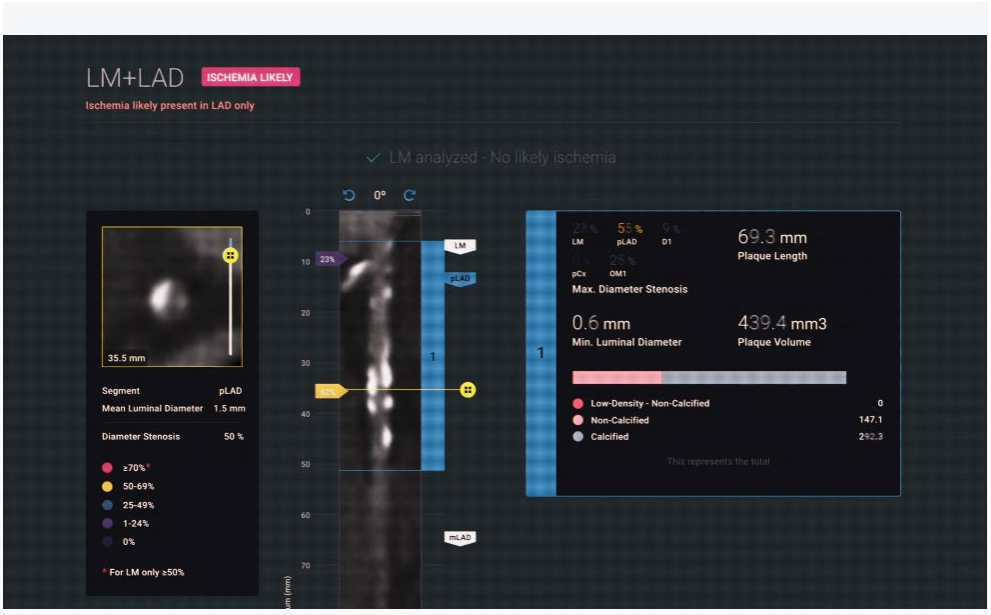
160. At least Claim 1 also requires executing, by the processor, the trained machine learning algorithm for at least a point of the geometric model of the image region of the patient to non-invasively determine values of the blood flow characteristic using the learned associations. Cleerly ISCHEMIA is described as a "heart disease evaluation that uses 37 measures of heart

health to determine likelihood of coronary artery ischemia at a per-vessel level" using "machine learning." Ex. 26 (Cleerly Non-Invasive Ischemia Analysis, https://cleerlyhealth.com/ischemia-reinvented). The Cleerly ISCHEMIA algorithm "outputs a CLEERLY ISCHEMIA Index (CII), a binary indication of likely ischemia regarding presence vs. absence for a given vessel, which is equivalent to invasive FFR ≤ 0.80 vs. > 0.80." (Bär et al., https://pmc.ncbi.nlm.nih.gov/articles/PMC11057943/).

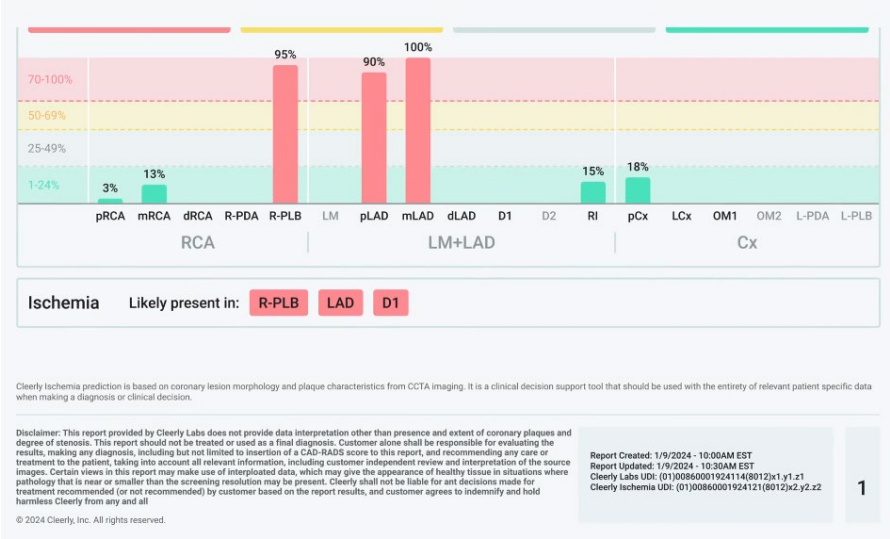


Ex. 26 (Cleerly Non-Invasive Ischemia Analysis, https://cleerlyhealth.com/ischemia-reinvented)

Cleerly ISCHEMIA is a first-of-its-kind, FDA-cleared heart disease evaluation that uses 37 measures of heart health to determine likelihood of coronary artery ischemia at a per-vessel level. Cleerly ISCHEMIA uses machine learning and concise reporting to aid physicians in personalizing patient treatment, including the planning of interventional treatments such as stent placement.



Id.



Id.

161. This determination is made non-invasively from CCTA data alone, using the learned associations developed during training on invasive FFR data from, for example, the CREDENCE and PACIFIC trial cohorts. Ex. 58 (Cleerly ISCHEMIA Demonstrates Robust Diagnostic Accuracy and Prognostic Utility, https://cleerlyhealth.com/press/cleerly-ischemia-diagnostic-accuracy-prognostic-utility).

162. Additional evidence of the Accused '569 Cleerly Products infringing Claims 1, 2, 4-9, 11-13, and 15-17 is included in the documents below, including representations Cleerly made in its FDA filings and details Cleerly disclosed about techniques it implements in the Accused '569 Cleerly Products in articles and appendices attached to the articles.

163. For example, an FDA submission dated September 22, 2020 includes representations by Cleerly that provide evidence of the Accused '569 Cleerly Products infringing one or more claims of the '569 Patent, including implementing "deep learning" and/or machine learning along with receiving images of anatomic structure, obtaining estimate of boundary, and implementing ISCHEMIA:

Device Name

Cleerly ISCHEMIA

Indications for Use *(Describe)*

Cleerly ISCHEMIA analysis software is an automated machine learning-based decision support tool, indicated as a diagnostic aid for patients undergoing CT analysis using Cleerly Labs software. When utilized by an interpreting healthcare provider, this software tool provides information that may be useful in detecting likely ischemia associated with coronary artery disease. Patient management decisions should not be made solely on the results of the Cleerly ISCHEMIA analysis.

Ex. 55 (FDA 510(k) Summary for Cleerly ISCHEMIA (K231335), https://www.accessdata.fda.gov/cdrh_docs/pdf23/K231335.pdf).

4. Device Description

Cleerly ISCHEMIA is an add-on software module to Cleerly Labs (K202280, K190868) that determines the likely presence or absence of coronal vessel ischemia based on quantitative measures of atherosclerosis, stenosis, and significant vascular morphology from typically-acquired Coronary Computed Tomography Angiography images (CCTA). Cleerly ISCHEMIA, in conjunction with Cleerly Labs, outputs a Cleerly ISCHEMIA Index (CII), a binary indication of negative CII (likely absence of ischemia) or positive CII (likely presence of ischemia) with its threshold equivalent to invasive FFR >0.80 vs. ≤0.80, respectively, as identified in professional societal practice guidelines.

Id.

The Cleerly ISCHEMIA data workflow begins after the Cleerly Labs outputs are approved for a study. A pre-processing module evaluates the eligibility of a study or vessels within the study for the Cleerly ISCHEMIA algorithm. The presence of certain identified anomalies can make an entire study ineligible, whereas the presence of a stent or exclusion in a vessel can make just that vessel ineligible. For all eligible vessels within a study, relevant Cleerly Labs outputs are aggregated from the default segment level to vessel level as the inputs to the Cleerly ISCHEMIA algorithm to determine the likely presence of ischemia. The results will then be evaluated by a post-processing module, which ensures that vessels subtended to a likely ischemic vessel are also marked as likely ischemic. The Cleerly ISCHEMIA algorithm outputs a Cleerly ISCHEMIA Index (CII), a binary indication of likely ischemia presence vs absence for a given vessel, which is equivalent to invasive FFR ≤0.80 vs. >0.80, respectively. Invasive FFR is a widely accepted gold-standard for determining vessel-specific ischemia. The Cleerly ISCHEMIA algorithm is "locked," meaning it is not a continuous learning algorithm.

Cleerly ISCHEMIA Index (likely ischemia / not likely ischemia) is displayed visually by Cleerly Labs to show the likely presence or absence of ischemia within epicardial coronary artery vessels. Vessels with Cleerly ISCHEMIA Index indicating likely ischemia presence (positive CII) are illuminated red, while vessels with Cleerly ISCHEMIA Index indicating likely ischemia absence (negative CII) are not illuminated. Cleerly ISCHEMIA analysis is intended to non-invasively support the functional evaluation of clinically stable symptomatic patients with coronary artery disease (CAD).

Id.

	disease)
Indications for Use	Cleerly ISCHEMIA analysis software is an automated machine learning-based decision support tool, indicated as a diagnostic aid for patients undergoing CT analysis using Cleerly Labs software. When utilized by an interpreting healthcare provider, this software tool provides information that may be useful in detecting likely ischemia associated with coronary artery disease. Patient management decisions should not be made solely on the results of the Cleerly ISCHEMIA analysis.

Id.

164. Additional FDA submissions dated September 22, 2020 and October 9, 2019 include representations by Cleerly that also provide evidence of the Accused '569 Cleerly Products infringing one or more claims of the '569 Patent:

Cleerly Labs is a web-based software application that is intended to be used by trained medical professionals as an interactive tool for viewing and analyzing cardiac computed tomography (CT) data for determining the presence and extent of coronary plaques (i.e., atherosclerosis) and stenosis in patients who underwent Coronary Computed Tomography Angiography (CCTA) for evaluation of CAD or suspected CAD. This software post processes CT images obtained using any Computed Tomography (CT) scanner. The software provides tools for the measurement and visualization of coronary arteries.

Cleerly 510(k) Summary, K202280, September 22, 2020 (Ex. 47)

4. Device Description

Cleerly Labs is a post-processing web-based software application that enables trained medical professionals to analyze 2D/3D coronary images acquired from Coronary Computed Tomography Angiography (CCTA) scans. The software is a post-processing tool that aids in determining treatment paths for patients suspected to have coronary artery disease (CAD).

Cleerly Labs utilizes machine learning and simple rule-based mathematical calculation components which are performed on the backend of the software. The software applies deep learning methodology to identify high quality images, segment and label coronary arteries, and segment lumen and vessel walls. 2D and 3D images are presented to the user for review and manual editing. This segmentation is designed to improve efficiency for the user, and help shorten tedious, time-consuming manual tasks.

Cleerly Labs provides a visualization of the Cleerly Labs analysis in the CORONARY Report. The CORONARY Report uses data previously acquired from the Cleerly Labs image analysis to generate a visually interactive and comprehensive report that details the atherosclerosis and stenosis findings of the patient. This report is not intended to be the final report (i.e., physician report) used in patient diagnosis and treatment. Cleerly Labs provides the ability to send the text report page of the CORONARY Report to the user's PACS system.

Id.

6. Software Functionality

In Cleerly Labs, users can edit the lumen and vessel walls of the suggested segmentation, and demarcate stenosis and stents, to more efficiently perform coronary analysis. Users are provided with navigation and editing/visualization tools to aid in image analysis. Plaque (i.e., atherosclerosis) and stenosis measurements are outputted based on the fully user-editable segmentation of the coronary artery. The user is also provided with the ability to indicate coronary anatomical findings.

Following the completion of study analysis, an interactive CORONARY Report is generated (the subject device of this submission). The CORONARY Report summarizes the analysis data from Cleerly Labs by reporting them as findings on atherosclerosis and stenosis, which may be used as supporting data in the evaluation of CAD. Components of the CORONARY Report include data visualization and reporting features. **Table 4** below compares the key features of the subject and predicate devices.

Id.

Device Description

Cleerly Labs is a post-processing web-based software application that enables trained medical professionals to analyze 2D/3D coronary images acquired from Computed Tomography (CT) angiographic scans. The software is a post-processing tool that aids in determining treatment paths for patients suspected to have coronary artery disease (CAD).

The output of the software includes visual images of coronary arteries, distance and volume measurements of the lumen wall, vessel wall, and plaque, remodeling index as well as stenosis diameter and area. These measurements are based on user segmentation.

Cleerly 510(k) Summary, K190868, October 9, 2019 (Ex. 48)

- A Usability test was conducted with U.S. board certified radiologists and technicians to ensure the clinical acceptability of the device.
- The machine learning algorithms were evaluated by comparing the output of the software to that of the ground truth using multiple ground truthers.

Id.

Visualization / Edit Tools	• Lumen Wall • Vessel Wall • Segment • Stenosis • Centerline • Plaque • Chronic Total Occlusion (CTO) • Stent • Exclude • Distance
2D Imaging	Yes
3D Imaging	Yes
Multiplanar Reformat (MPR)	Yes
Segmentation of region of interest	Manual and Semi-Automatic

Quantification	
Hounsfield Unit (HU)	Yes
Distance Measurements	• Vessel • Lesion • Length
Volumetric Measurements	• Total Vessel • Total Lumen • Non-Calcified Plaque (NCP) • Low-Density Non-Calcified Plaque (LD-NCP) • Calcified Plaque (CP) • Total Plaque
Remodeling Index	Yes
Stenosis	• % Area Stenosis • % Diameter Stenosis

Id.

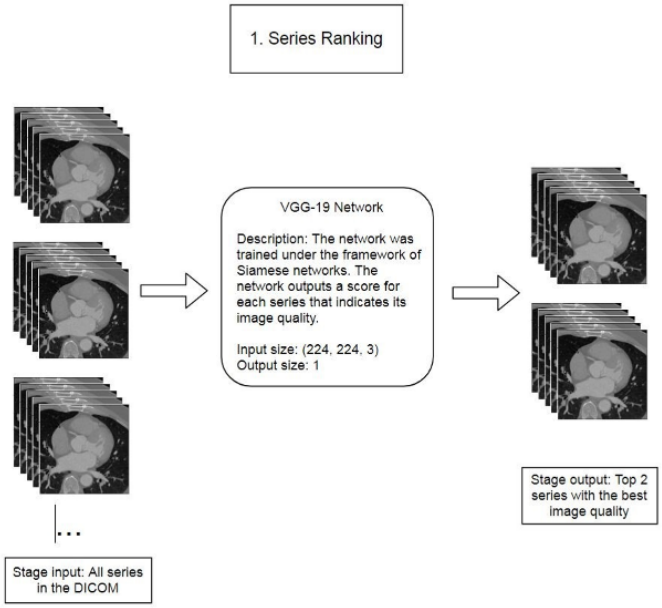
165. Further, upon information and belief, the following publication provides evidence of specific techniques implemented by the Accused '569 Cleerly Products, including the use of CNN, determining stenosis, implementing machine learning, providing "scores," generating 3D

models, identifying dimensions, plaque quantification, and/or additional features demonstrating that the Accused '569 Cleerly Products infringe one or more claims of the '569 Patent:

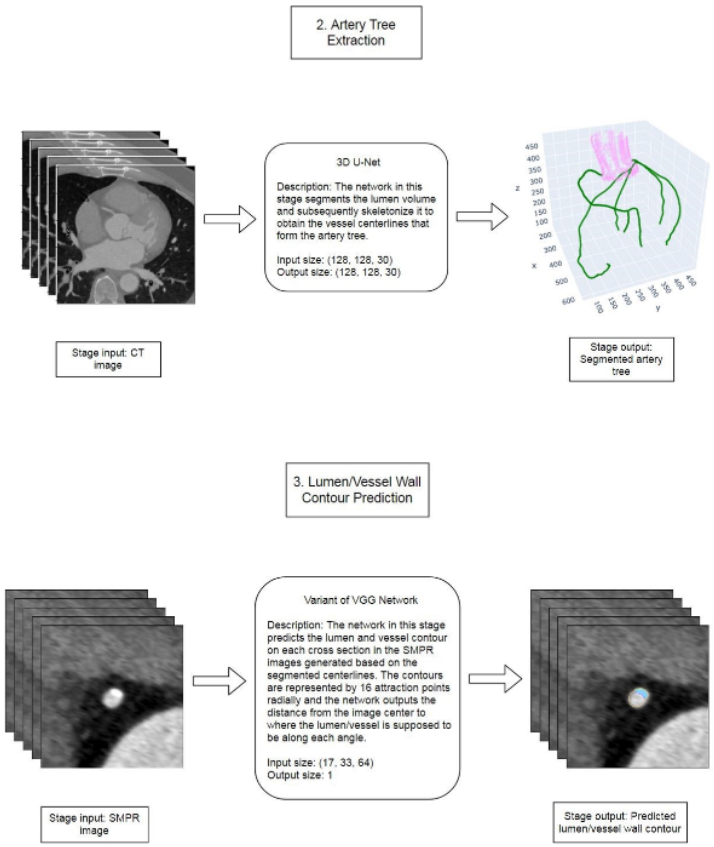
Appendix B: Artificial Intelligence/Machine Learning Steps to CCTA Image Evaluation: The following figures present in graphical detail the stepwise use of artificial intelligence algorithms used for CCTA analysis.

This is an AI-aided approach (Cleerly Inc, New York, NY) that performs an automated analysis of CCTA using a series of validated convolutional neural network models (including VGG 19 network, 3D U-Net and VGG Network Variant) for image quality assessment, coronary segmentation and labeling, lumen wall evaluation and vessel contour determination and plaque characterization(19). No manual interaction is required from the reader. First, the AI-aided approach leverages 2 deep convolutional neural networks (VGG-19 Network and 3D U-Net) to produce a centerline along the length of the vessel, and then for lumen and outer vessel wall contouring. This approach is applied to multiple phases/series of the CCTA examination, if present, and enables phase-specific evaluation at the coronary segment vessel. The algorithm reviewed all series and determined the top 2 optimal series for further analysis including vessel and lumen segmentation, plaque, and stenosis quantification. The algorithm rank-orders all available phases for the segmentation of the arteries. It then uses the top two phases interactively on a per vessel basis, e.g., the right coronary artery (RCA) will be reconstructed from the phase which yields the highest RCA image quality, while the posterior descending artery (PDA) may come from the second phase if the PDA has a higher image quality on that phase. Once coronary artery segmentation is performed, an automated labeling is done to classify arteries by their location as well the proximal, mid and distal portions within a single vessel. The AI further allows for defining of coronary artery lesions (i.e., those areas where plaque is present; VGG Network Variant). Utilizing a normal proximal reference vessel cross-sectional slide, the start and the end of the lesion, and the cross-sectional slice that demonstrates the greatest absolute narrowing, % diameter stenosis severity is automatically calculated. The software determines the start and end of lesions and drops stenosis markers at the region of the highest stenosis. Within coronary artery lesions, plaque is quantified in a similar fashion, and further characterized as low-attenuation non-calcified plaque, non-calcified plaque and calcified plaque based upon Hounsfield unit (HU) densities of <30, -189 to 350, >350, respectively. Positive arterial remodeling was identified as a remodeling index ≥1.10 by diameter when compared to a proximal vessel reference. Vessel length, vessel volume, lumen volume, total plaque volume, calcified plaque volume, noncalcified plaque volume, low density noncalcified plaque volume, maximum diameter and area stenosis, and maximum remodeling index are calculated.

Choi AD, et al. CT Evaluation of Coronary Artery Disease by AI: Appendix B (Ex. 49)



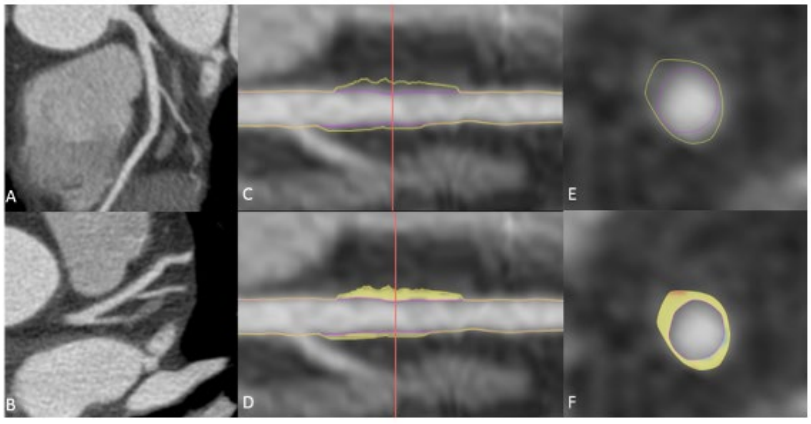
Id.



Id.

Supplement Figure 2: Contingency Tables of Level 3 Reader vs AI CAD-RADS Scores by CAD-RADS 0-3 and 4-5. These categories were chosen to represent a medical therapy (<70% stenosis) vs interventional (>70%) treatment threshold. On a per-vessel and per-patient basis, L3 and AI had 99.9% and 99.6% category agreement for these thresholds with weighted kappa values of 0.96 and 0.95 respectively.

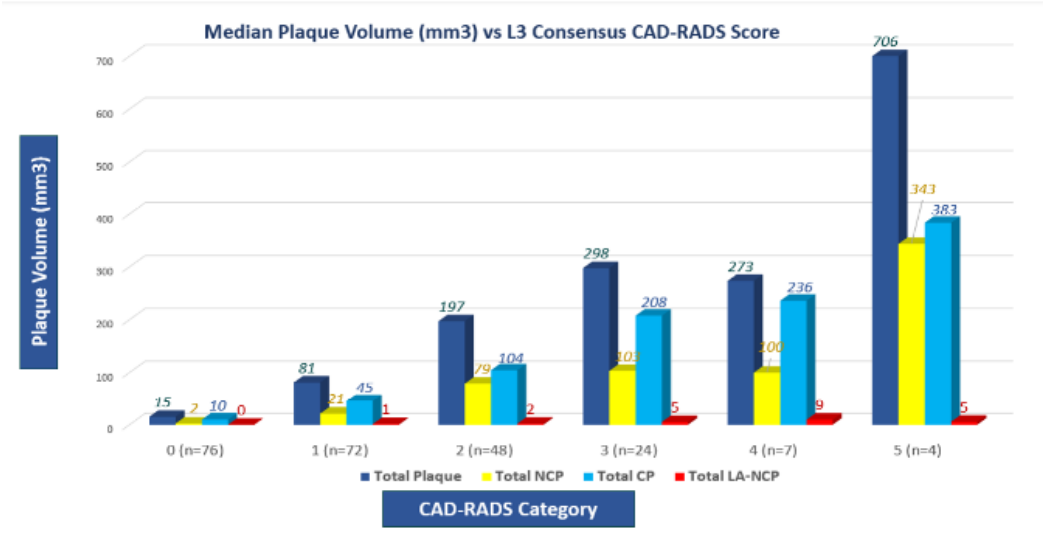
Choi AD, et al. CT Evaluation of Coronary Artery Disease by AI: Appendix A (Ex. 50)



Id.

Supplement Figure 3: Example case of discordance between AI and Level 3 Expert Consensus. The most common disagreement between expert consensus reads and AI reads was expert consensus CAD-RADS 0 and AI CAD-RADS 1. In this example of a 56-year-old male with dyspnea and a strong family history of CAD, the expert consensus read was a CAD-RADS 0 with no stenosis and no plaque (Panel A: Proximal and mid left anterior descending coronary artery curved multiplanar reformation [MPR]; Panel B: axial image of proximal and mid left anterior descending). The AI depicted 82 mm^3 of circumferential noncalcified plaque in the mid LAD with no coronary stenosis (Panel C: A straightened MPR depicting AI segmentation of the lumen boundary [purple line] and outer vessel wall [yellow line], Panel D: Same image as Panel C with a color overlay of noncalcified plaque (density >30 and < 350 HU), Panel E: A short axis MPR generated at the mid plaque level [red line] from image C again depicting lumen [purple] and vessel wall outer boundaries [yellow]; Panel F: Same as Panel E with color overlay of the noncalcified plaque [density >30 and < 350 HU]).

Id.



Supplemental Figure 4: **Median AI quantified plaque volume vs Level 3 Consensus by CAD-RADS Categorization**. Quantified plaque volume showed a broad range of values across CAD-RADS categories. NCP = Non-calcified plaque; CP = Calcified plaque; LA-NCP = Low attenuation non-calcified plaque

Id.

166. Further, upon information and belief, the functionality of the Accused '569 Cleerly Products is described in the paper titled "CT Evaluation by Artificial Intelligence for Atherosclerosis, Stenosis and Vascular Morphology (CLARIFY): A Multi-center, international study" (Ex. 51), which also provides additional evidence that the Accused '569 Cleerly Products infringe one or more claims of the '569 Patent:

Artificial Intelligence Segmentation and Plaque Quantification. CCTA studies were uploaded to and analyzed by FDA-cleared software Cleerly LABS (Cleerly, New York, New York).[17,18] The three sites contributing cases were not used for software development or validation. This study is an investigator initiated study and Cleerly had no role in the study design or performance. Cleerly performed AI-aided CCTA analyses for the study in a blinded manner, and provided statistical services as determined and requested by study investigators.

This is an AI-aided approach (**Central Illustration**) that performs automated analysis of CCTA using a series of validated convolutional neural network models (including VGG 19 network, 3D U-Net and VGG Network Variant) for image quality assessment, coronary segmentation and labeling, lumen wall evaluation and vessel contour determination and plaque characterization.[10,19] A full graphical representation of the algorithm with validation details is presented in Appendix B. First, the AI-aided approach leverages 2 deep convolutional neural networks to

Id.

quantification. The algorithm rank-orders all available phases for the segmentation of the arteries. It then uses the top two phases interactively on a per vessel basis, e.g., the right coronary artery (RCA) will be reconstructed from the phase which yields the highest RCA image quality, while the posterior descending artery (PDA) may come from the second phase if the PDA has a higher image quality on that phase. Once coronary artery segmentation is performed, an automated labeling is done to classify arteries by their location as well the proximal, mid and distal portions within a single vessel. The AI further allows for defining of coronary artery lesions (i.e., those areas where plaque is present). Uti-

Id.

L3 readers determined maximum diameter stenosis was compared with AI stenosis on a per-patient and per-vessel basis. Correlation and numeric agreement were assessed. The Pearson correlation coefficient was used to evaluate correlation, linear regression plots were generated for visualization of the relationship. Bland-Altman plots with limits of agreement was performed. Diagnostic performance of AI vs L3 was assessed through diagnostic accuracy, sensitivity, specificity, positive and negative predictive values at both >50% and >70% stenosis thresholds on per vessel and per patient basis.

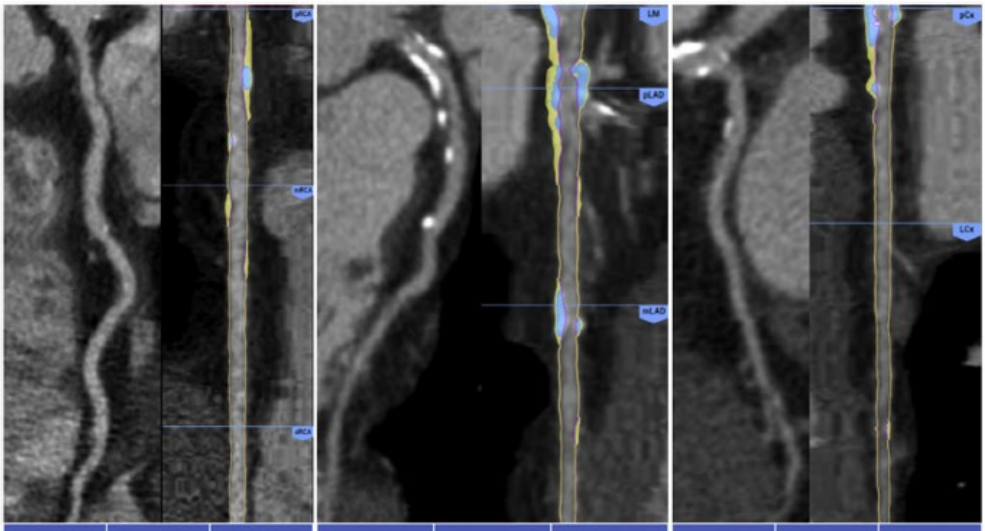
Id.

Readers determined presence of two high risk plaque features—low attenuation plaque <30 Hounsfield units (HU) and positive arterial remodeling with a remodeling index ≥1.10 by diameter—with this analysis compared with AI on per vessel and per patient basis. This binary outcome was compared by calculating the percent agreement and kappa statistic.

Id.

CAD-RADS Categorization. Fig. 1 depicts consensus reads versus AI results. Overall, 182/232 (78.0%) had CAD-RADS categorical agreement, 228/232(98.3%) agreed within one category. The most frequent disagreement occurred with expert consensus CAD-RADS 0 and AI CAD-RADS 1 (n = 29 12.5% per patient, n = 161 17.4% per vessel). To further evaluate L3 consensus vs AI for a collated mild-moderate versus severe stenosis categories, at a threshold for potential interventional treatment (>70% stenosis), we evaluated CAD-RADS 0–3 and CAD-RADS 4–5 to assess accuracy and found only 1 case of discrepancy on either a per-

Id.



	Consensus	AI
RCA	26%	35%

	Consensus	AI
Left Main	55%	60%
LAD	53%	47%

	Consensus	AI
Circumflex	24%	34%

Id.

Machine Learning Applied to CCTA. Recent studies have begun to evaluate individual aspects of AI-enabled plaque quantification, though few of these solutions are currently available clinically. Zreik et al. used a multitask recurrent convolutional neural network in n = 166 for automatic characterization of plaque.[38] They achieved a linearly weighted kappa of 0.68, 0.66 and 0.67 at the segment, artery and patient-level for the binary presence or absence of non-calcified, mixed and calcified plaque. Kang et al. used a support vector machine (SVM) learning algorithms in a small number of datasets (n = 42) for detection of plaque for lesions a simplistic severity of ≥25% in comparison to experienced expert consensus readers and reported accuracy of 94%.[39]

Id.

167. The foregoing features and capabilities of each of the Accused '569 Cleerly Products description and/or demonstration thereof, including in advertising, reflect Cleerly's direct infringement by satisfying every element of at least Claims 1, 2, 4-9, 11-13, and 15-17 of the '569 Patent under 35 U.S.C. § 271(a).

168. Upon information and belief, Cleerly has induced infringement, and continues to induce infringement, of one or more Claims 1, 2, 4-9, 11-13, and 15-17 of the '569 Patent by actively and knowingly inducing others, including health care providers and hospitals in the Eastern District of Texas and throughout the United States, to directly infringe one or more claims of the '569 Patent through the use of Cleerly's products and services. For example, Cleerly instructs hospital employees and doctors, and induces patients through its website, via generating tutorial videos for training purposes, training hospital employees, conducting webinars, conducting demos at events, and/or producing instructional videos to induce them to directly infringe one or more claims of the '569 Patent through the use of the Accused '569 Cleerly Products. *See* https://www.youtube.com/@cleerlyhealth/videos (Ex. 42); https://cleerlyhealth.com/clinical-publications; https://cleerlyhealth.com/blog; https://cleerlyhealth.com/webinars; https://cleerlyhealth.com/events.

169. Upon information and belief, Cleerly has contributed to the infringement of one or more of Claims 1, 2, 4-9, 11-13, and 15-17 of the '569 Patent by providing products and services that constitute material parts of the claimed inventions, knowing the same to be especially made or adapted for use in an infringing manner. For example, the Accused '569 Cleerly Products include at least one component to generate images and implement CNN to be used in conjunction with the Cleerly Platform to perform CAD detection. This is a component of a patented machine, manufacture, or combination, or an apparatus for use in practicing a patented process. Furthermore, such component is a material part of the invention and upon information and belief is not a staple article or commodity of commerce suitable for substantial non-infringing use. Thus, Cleerly is liable for infringement of the '569 Patent pursuant to 35 U.S.C. § 271(c).

170. Upon information and belief, Cleerly has been on notice of the '569 Patent at least since its issuance, and Cleerly's infringement of the '569 Patent has been and continues to be willful. For example, Cleerly, through its founder, Dr. James K. Min, had actual knowledge of Heartflow's patent portfolio through Dr. Min's role as a Heartflow consultant from 2012 to 2017, his execution of an NDA and Consulting Agreement with Heartflow, and his role as lead investigator on Heartflow's DeFACTO study. Dr. Min incorporated Cleerly on July 19, 2016 while still subject to the Consulting Agreement and its confidentiality, non-compete, and invention assignment obligations. Cleerly further acquired actual knowledge of Heartflow's patents through its hiring of Brent Ness, Heartflow's former Chief Commercial Officer, who was bound by confidentiality obligations under the Ness Agreement and Separation Agreement. Cleerly has knowledge about the '569 Patent based on Cleerly citing the '569 Patent repeatedly in its own patents as seen below:

Heartflow's Patent	**Cleerly Patent Citing Heartflow's Patent**
US11382569B2	US11642092B1 US11660058B2 US11690586B2 US11861833B2 US11922627B2 US12144669B2 US12380560B2 US12440180B2

171. By the time of trial, Cleerly will thus have known and intended (since receiving such notice), that its continued actions would actively induce and contribute to actual infringement of one or more Claims 1, 2, 4-9, 11-13, and 15-17 of the '569 Patent.

172. Despite this actual knowledge of Heartflow's patents, Cleerly deliberately chose to develop and commercialize infringing products rather than seek a license of those patents.

173. Cleerly undertook and continues its infringing actions despite an objectively high likelihood that such activities infringed the '569 Patent, which has been duly issued by the USPTO and is presumed valid. For example, Cleerly has been aware of an objectively high likelihood that its actions constituted, and continue to constitute, infringement of the '569 Patent based on Dr. Min's actual knowledge and Cleerly's knowledge as shown on Cleerly's own patents, and that the '569 Patent is valid. On information and belief, Cleerly cannot reasonably, subjectively believe that its actions do not constitute infringement of the '569 Patent, nor could it reasonably, subjectively believe that the patent is invalid. Despite that knowledge and subjective belief, and the objectively high likelihood that its actions constitute infringement, Cleerly has continued its infringing activities. As such, Cleerly willfully infringes the '569 Patent.

174. Heartflow has been damaged by Cleerly's infringement of the '569 Patent and is entitled to recover damages adequate to compensate for such infringement pursuant to 35 U.S.C. § 284.

COUNT 3 – CLEERLY'S INFRINGEMENT OF U.S. PATENT NO. 9,770,303

175. Heartflow incorporates all preceding paragraphs by reference.

176. U.S. Patent No. 9,770,303 (the "'303 Patent") was duly issued on September 26, 2017, and is titled "Systems and methods for predicting coronary plaque vulnerability from patient-specific anatomic image data." A copy of the '303 Patent is attached as Exhibit 9.

177. Heartflow is the owner by assignment of the '303 Patent and possesses all rights under the '303 Patent, including the exclusive right to recover for past and future infringement.

178. The '303 Patent is directed to systems and methods for predicting coronary plaque vulnerability from patient-specific anatomic image data. For example, the '303 Patent discloses a computer-implemented method of predicting a cardiac risk of a patient, the method comprising:

acquiring anatomical image data of at least part of a patient's vascular system; performing, using a processor, one or more of image characteristics analysis, geometrical analysis, computational fluid dynamics analysis, and structural mechanics analysis on the anatomical image data; determining, using the processor, a coronary plaque vulnerability present at a selected location in the patient's vascular system based on results of one or more of the image characteristics analysis, geometrical analysis, computational fluid dynamics analysis, and structural mechanics analysis of the anatomical image data; acquiring image data of each individual in a plurality of individuals; determining a model of vascular geometry present in each individual in the plurality of individuals other than the patient, wherein each model comprises one or more points; determining, for each individual's model, a selected point corresponding to the selected location in the patient's vascular system; determining, for each selected point of each individual's model, an individual-specific numerical description of one or more factors that affect cardiac risk; generating, for the selected location of the patient's vascular system, a patient-specific numerical description of one or more factors that affect cardiac risk based on each of the individual-specific numerical descriptions; and predicting a cardiac risk of the patient based on (i) the determined coronary plaque vulnerability present at the location in the patient's vascular system and (ii) the patient-specific numerical description.

179. The '303 Patent explains that, at the time of its priority date, coronary artery disease could produce coronary lesions in the blood vessels providing blood to the heart, such as a stenosis, and that a more severe manifestation of disease could lead to myocardial infarction, or heart attack. '303 Patent at 1:28-36. Patients suffering from symptoms of coronary artery disease could be subjected to noninvasive tests, including electrocardiograms, biomarker evaluation, treadmill tests, echocardiography, and imaging modalities such as coronary computed tomographic angiography

(CCTA). *Id.* at 1:37-49. Meanwhile, vulnerable plaque features, such as adverse plaque characteristics (APCs), had been actively investigated for prognosis of major adverse cardiac events (MACE) using both invasive and noninvasive techniques, such as intravascular ultrasound, optical coherence tomography, and CCTA. *Id.* at 1:51-57. However, a need existed for improved systems and methods for predicting coronary plaque vulnerability from patient-specific anatomic image data. *Id.* at 1:58-60.

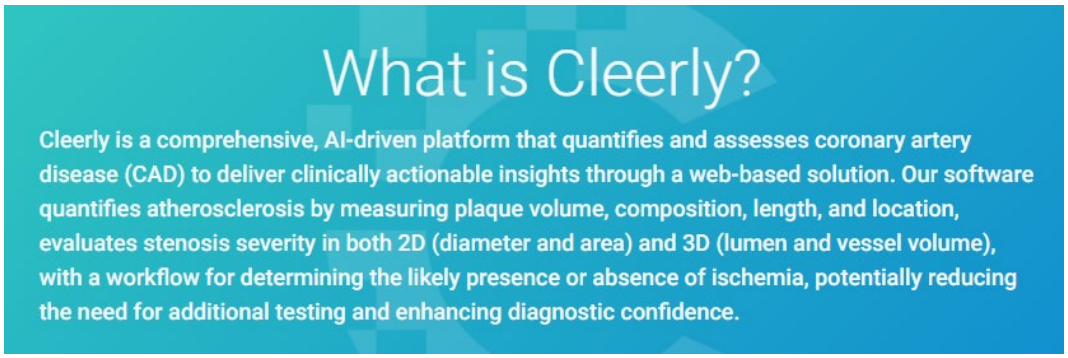
180. The '303 Patent solved these problems by providing systems and methods for defining coronary plaque vulnerability from patient-specific anatomic image data. *Id.* at 5:47-6:5. More specifically, the claimed invention acquires anatomical image data of at least part of a patient's vascular system and performs, using a processor, one or more of image characteristics analysis, geometrical analysis, computational fluid dynamics analysis, and structural mechanics analysis on the anatomical image data.

181. Using the results of these analyses, the claimed invention determines a coronary plaque vulnerability present at a selected location in the patient's vascular system. The claimed invention further acquires image data of each individual in a plurality of individuals and determines a model of vascular geometry present in each individual other than the patient, wherein each model comprises one or more points. For each individual's model, a selected point corresponding to the selected location in the patient's vascular system is determined, and, for each such selected point, an individual-specific numerical description of one or more factors that affect cardiac risk is determined. Accordingly, for the selected location of the patient's vascular system, a patient-specific numerical description of one or more factors that affect cardiac risk is generated based on each of the individual-specific numerical descriptions. The cardiac risk of the patient is then predicted based on both the determined coronary plaque vulnerability present at the location

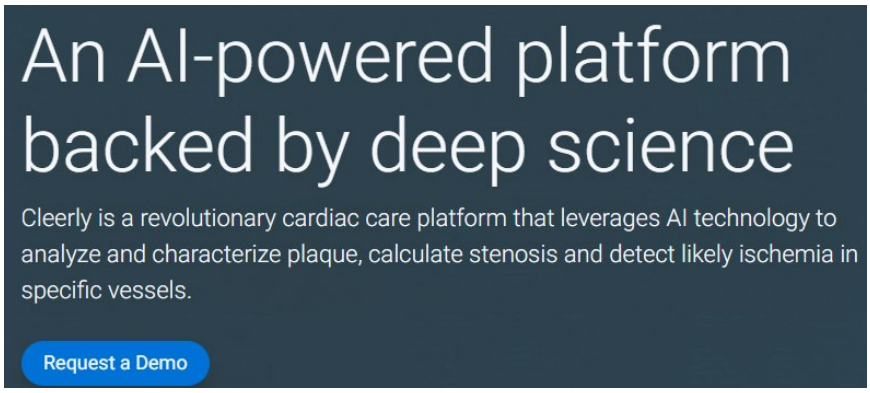
in the patient's vascular system and the patient-specific numerical description. Therefore, a computer-implemented method of predicting cardiac risk with improved accuracy through the integration of plaque vulnerability analysis and patient-specific numerical descriptions derived from a plurality of individuals is achieved.

182. Evidence that the '303 Patent is valid and is directed to novel and inventive technology is discussed above in at least paragraphs 17-41 and 96-103 and incorporated by reference. Further, the '303 Patent has been recognized as a foundational patent as shown by the fact that it has been cited in over 111 additional patents, including patents filed by Stenomics, Inc., Siemens Healthcare GmbH, Elucid Bioimaging Inc., Cleerly, and Emory University.

183. Upon information and belief, Cleerly has directly infringed, and continues to directly infringe, one or more claims of the '303 Patent in this District and elsewhere in Texas, including at least Claims 1, 3-5, 7, 9, 11-13, 15, 17, 19, and 20 literally and/or under the doctrine of equivalents, making, using, selling, offering to sell, and/or importing into the United States products and services that practice the inventions claimed therein, including, but not limited to, Cleerly Plaque Analysis ("the Accused '303 Cleerly Product"). For example, Cleerly provides a "comprehensive, AI-driven platform that quantifies and assesses coronary artery disease (CAD)" that "quantifies atherosclerosis by measuring plaque volume, composition, length, and location, evaluates stenosis severity in both 2D (diameter and area) and 3D (lumen and vessel volume), with a workflow." https://cleerlyhealth.com/ (Ex. 29).



https://cleerlyhealth.com/ (Ex. 29)

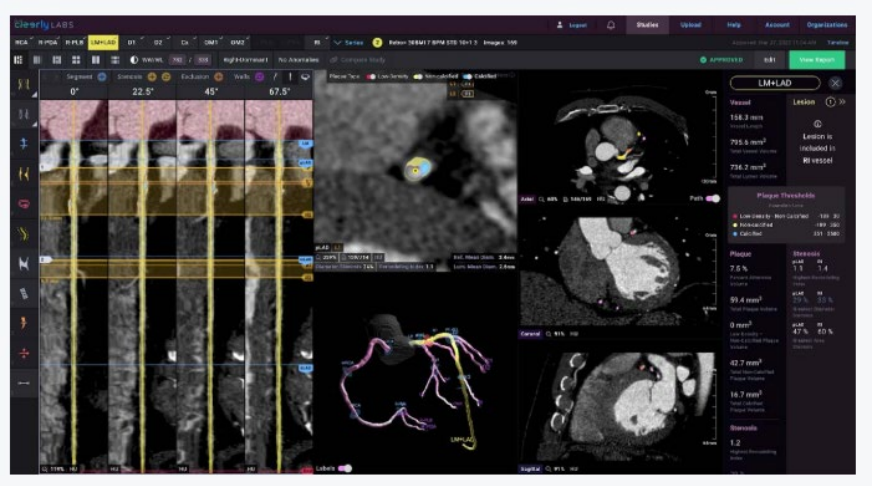


https://cleerlyhealth.com/what-is-cleerly (Ex. 41)

Cleerly uses proprietary and FDA-cleared machine learning algorithms to non-invasively measure atherosclerosis (plaque), stenosis, and likelihood of ischemia using coronary computed tomography angiography (CCTA) studies.

Our machine-learning AI generates a 3D model of the patient's coronary arteries, identifies their lumen and vessel walls, locates and measures stenoses, while quantifying and categorizing plaque.[1] Cleerly ISCHEMIA's algorithm uses measurements based on invasive FFR data to determine the likelihood of vessel-level ischemia.[2]

https://cleerlyhealth.com/what-is-cleerly (Ex. 41)



https://cleerlyhealth.com/what-is-cleerly (Ex. 41)

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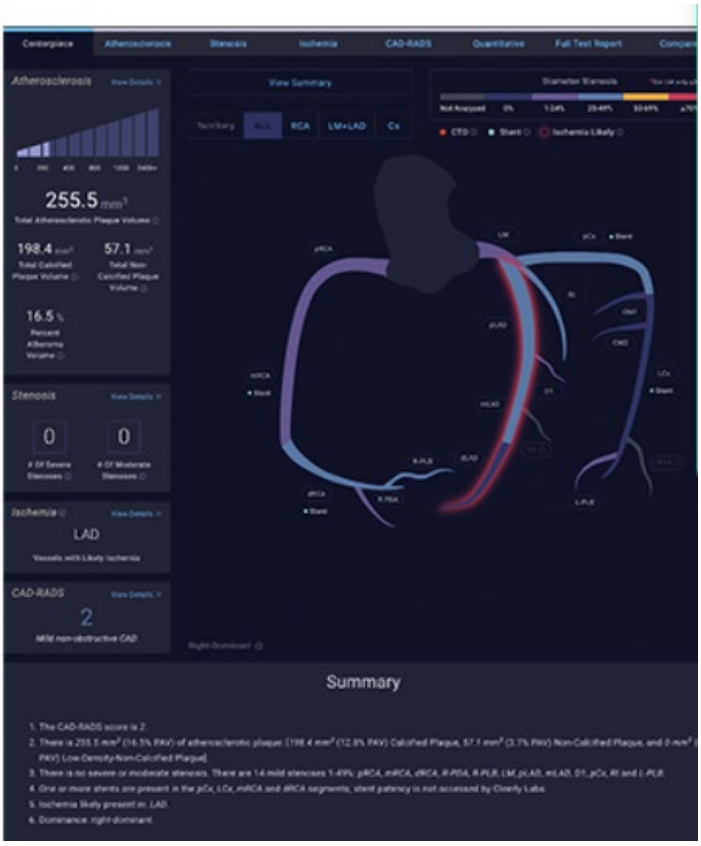
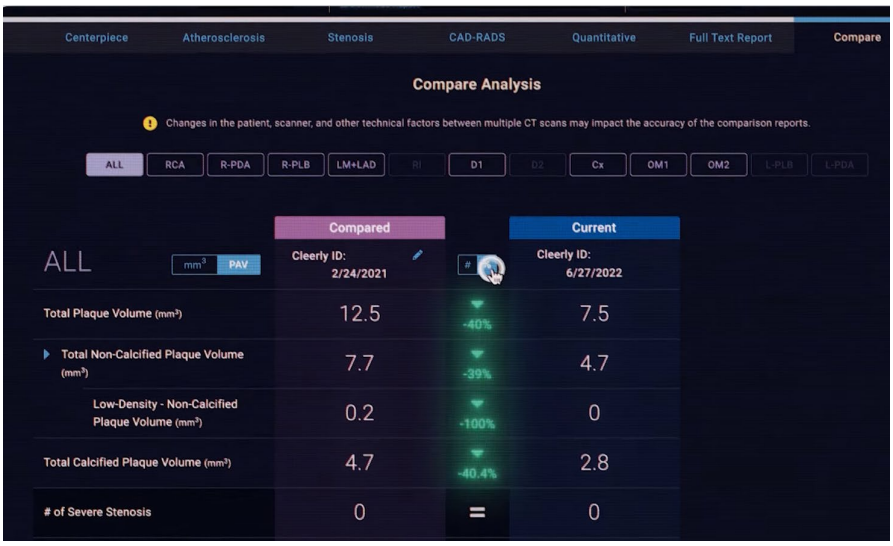
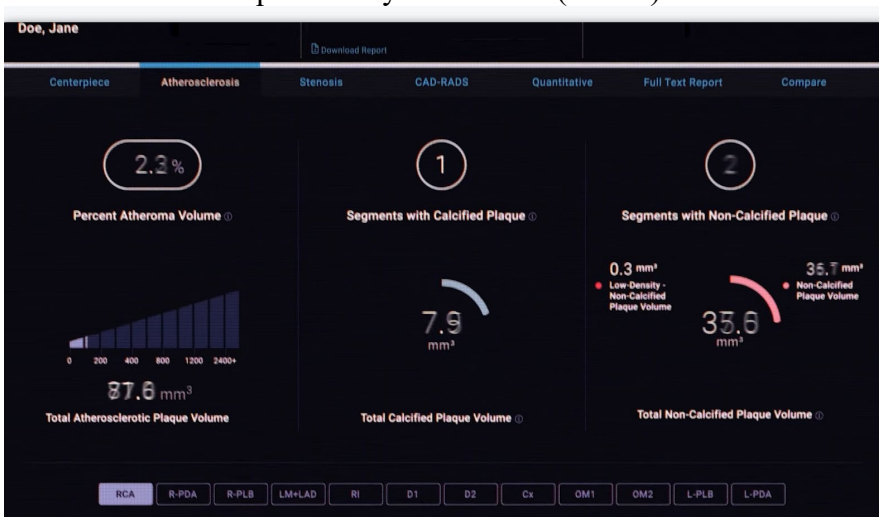
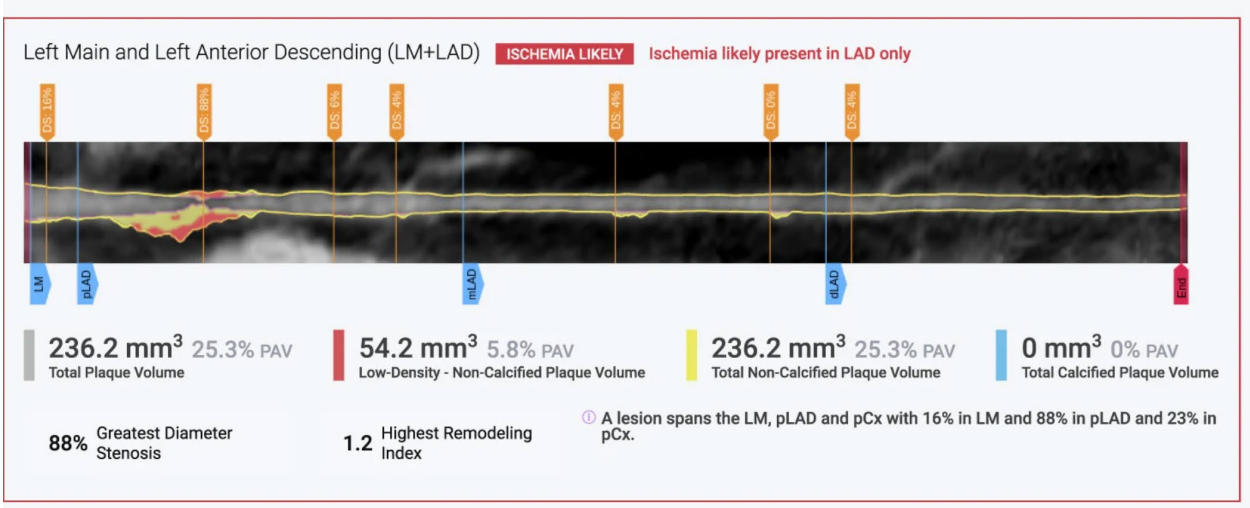




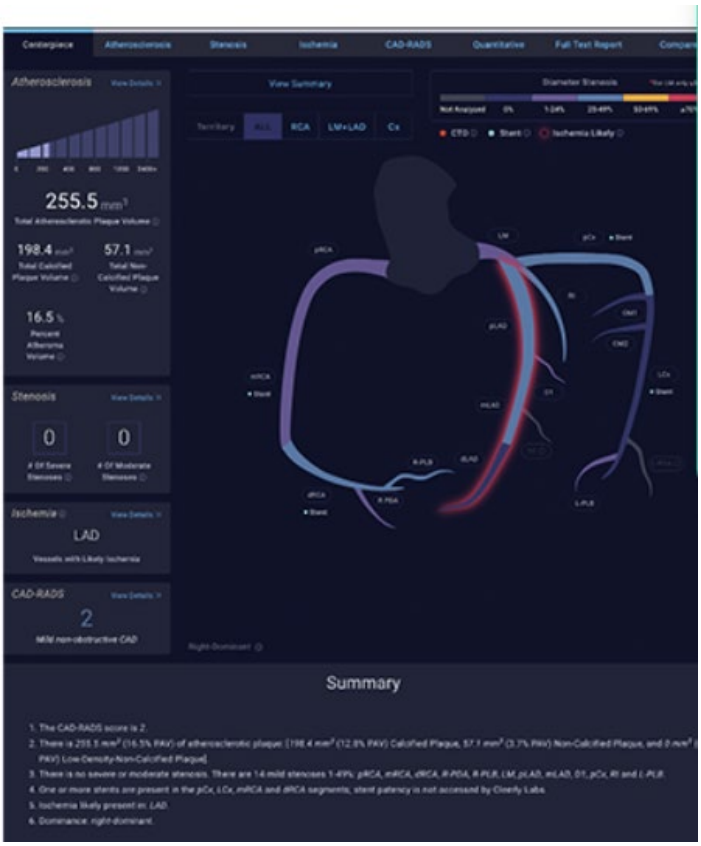
https://cleerlyhealth.com/ (Ex. 29)



https://cleerlyhealth.com/ (Ex. 29)



https://cleerlyhealth.com/patient-education (Ex. 35)

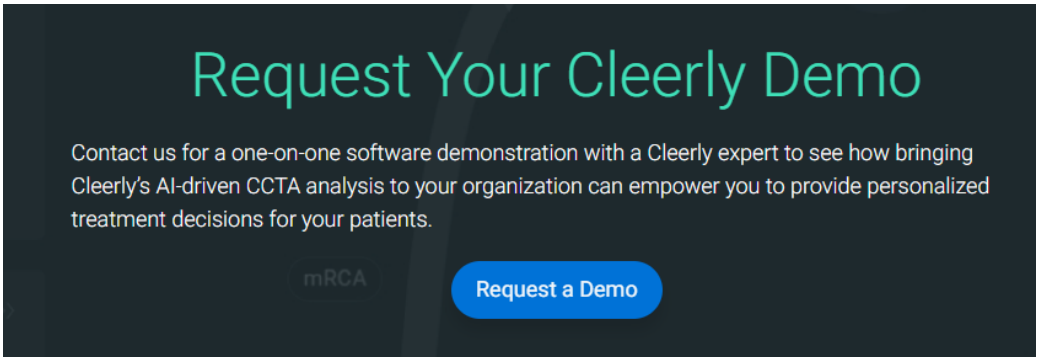


https://cleerlyhealth.com/what-is-cleerly (Ex. 41)

184. Heartflow reserves the right to discover and pursue any additional infringing products and services that incorporate infringing functionalities. For the avoidance of doubt, the Accused '303 Cleerly Product is identified to describe Cleerly's infringement and in no way limits the discovery and infringement allegations against Cleerly concerning other products that incorporate the same or reasonably similar functionalities.

185. Upon information and belief, Cleerly directly infringes by performing one or more method claims in the United States when, for example, performing testing, including "usability tests" as confirmed in FDA submissions, generating tutorial videos for training purposes, training hospital employees, conducting webinars, conducting demos at events, and/or producing instructional videos showing how the Accused '303 Cleerly Products operate. https://www.youtube.com/@cleerlyhealth/videos (Ex. 42); https://cleerlyhealth.com/clinical-

publications; https://cleerlyhealth.com/blog; https://cleerlyhealth.com/webinars; https://cleerlyhealth.com/events.



186. The Accused '303 Cleerly Product, either alone or in combination with other systems or products, performs a computer-implemented method of predicting a cardiac risk of a patient.

187. At least Claim 1 requires acquiring anatomical image data of at least part of a patient's vascular system. In clinical use, Cleerly acquires and analyzes a patient's coronary computed tomography angiography (CCTA) images, which are noninvasive imaging studies of the patient's coronary arteries. Ex. 41 (What is Cleerly, https://cleerlyhealth.com/what-is-cleerly). Cleerly uses "proprietary and FDA-cleared machine learning algorithms to non-invasively measure atherosclerosis (plaque), stenosis, and likelihood of ischemia using coronary computed tomography angiography (CCTA) studies." *Id.*

188. At least Claim 1 also requires performing, using a processor, one or more of image characteristics analysis, geometrical analysis, computational fluid dynamics analysis, and structural mechanics analysis on the anatomical image data. As an example, Cleerly's software "utilizes a series of validated convolutional neural network models (VGG 19 network, 3D U-Net, VGG Network Variant) for image quality assessment, coronary segmentation/labeling, lumen evaluation and contour determination, as well as plaque characterization." Ex. 60 (Cho et al., Serial

analysis of coronary artery disease progression by artificial intelligence assisted coronary computed tomography angiography, https://pmc.ncbi.nlm.nih.gov/articles/PMC9701371/). Cleerly's "machine-learning AI generates a 3D model of the patient's coronary arteries, identifies their lumen and vessel walls, locates and measures stenoses, while quantifying and categorizing plaque," which encompasses both image characteristics analysis and geometrical analysis of the anatomical image data. Ex. 41 (What is Cleerly, https://cleerlyhealth.com/what-is-cleerly). Cleerly's Plaque Analysis product further provides "vessel-by-vessel detail" with "phenotyping for each artery and branch with stenosis quantification and vascular remodeling scores," constituting geometrical analysis of the coronary vasculature. Ex. 52 (Cleerly Coronary Plaque Analysis, https://cleerlyhealth.com/plaque-analysis). Cleerly is classified alongside other CTA automated quantitative software tools that perform HU-based plaque characterization, which is a form of image characteristics analysis. Ex. 61 (Varga-Szemes et al., Computed Tomography Assessment of Coronary Atherosclerosis, https://pmc.ncbi.nlm.nih.gov/articles/PMC10287054/).

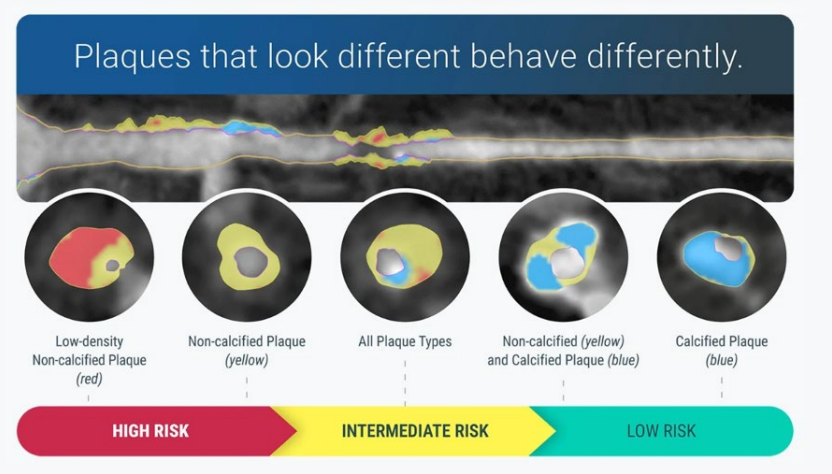
189. At least Claim 1 also requires determining, using the processor, a coronary plaque vulnerability present at a selected location in the patient's vascular system based on results of one or more of the image characteristics analysis, geometrical analysis, computational fluid dynamics analysis, and structural mechanics analysis of the anatomical image data. Upon information and belief, Cleerly identifies high-risk plaque characteristics that are recognized markers of coronary plaque vulnerability, including "Positive Remodeling: When arteries expand outward to accommodate plaque – a sign of vulnerability," and "Low Attenuation Plaque: Very soft plaque with lipid content, the most dangerous type." (Cleerly Heart Scan, https://craftconcierge.com/blog/cleerly-heart-scan-ai-technology-guide/). Jim Min was an author of Cleerly's CONFIRM2 registry and confirmed that Cleerly's product's "comprehensive analysis

of patient specific parameters of vulnerability will assist in advancing precise and personalized medicine" https://www.sciencedirect.com/science/article/pii/S1934592523004549 (Ex. 63). Cleerly's press release on their plaque product's data states how plaque quantification can be used to assess vulnerability of plaque: "This signifies a sufficient burden of plaque in non-obstructive disease may result in a critical mass of vulnerable disease that would warrant earlier intervention." https://cleerlyhealth.com/press/cvct-2025-cleerly-late-breaking-science (Ex. 64). Cleerly's CT sites advertise that "Using AI-powered coronary CT angiography, the Cleerly heart scan doesn't just tell you if plaque exists. It quantifies exactly how much plaque you have, identifies which lesions are vulnerable to rupture" https://craftconcierge.com/blog/cleerly-heart-scan-ai-technology-guide/.

190. Cleerly quantifies these features on a per-lesion and per-vessel basis, producing assessments of plaque vulnerability at specific locations within the coronary vasculature. Ex. 52 (Cleerly Coronary Plaque Analysis, https://cleerlyhealth.com/plaque-analysis). Clinical studies using Cleerly have validated that the "presence of 2 high-risk plaque characteristics (low-attenuation plaque and positive remodeling)"—as identified by Cleerly's AI-QCT analysis—are associated with adverse cardiac outcomes. Ex. 62 (Nurmohamed et al., AI-Guided Quantitative Plaque Staging Predicts Long-Term Cardiovascular Outcomes, https://www.jacc.org/doi/10.1016/j.jcmg.2023.05.020). Cleerly's plaque characterization thus functions as a determination of coronary plaque vulnerability at selected locations.

191. Cleerly also quantifies non-calcified plaque volume for lesions, vessels, and the patient, which they claim as "high risk" and "ACC/AHA guidelines highlight the importance of plaque, particularly high-risk plaque, as a driver of major adverse cardiovascular events (MACE)." https://cleerlyhealth.com/plaque-analysis (Ex. 52). Cleerly explains that plaque volume can lead

to heart attack: "The total amount of atherosclerosis in artery walls. High plaque volume can indicate a lifetime risk for future heart attacks" and the their product shows "Yellow plaque is non-hardened plaque and red plaque is high-risk soft plaque." And "Some types of plaque put you at a higher risk of heart attack. Non-calcified, low-density plaques are considered higher risk, because they are less stable than calcified plaques.1 When a non-calcified plaque ruptures, it can cause a heart attack." https://cleerlyhealth.com/patient-education (Ex. 35) and https://cleerlyhealth.com/heart-scan-faqs (Ex. 65):



192. At least Claim 1 also requires acquiring image data of each individual in a plurality of individuals; determining a model of vascular geometry present in each individual in the plurality of individuals other than the patient, wherein each model comprises one or more points. Cleerly's technology is "based on over 10 million images from over 40,000 patients gathered over a 15-year-period in landmark, multi-center clinical trials." Ex. 57 (Cleerly Atherosclerosis, Stenosis and Ischemia Analysis, https://cleerlyhealth.com/diagnosing-cad). Its AI algorithms were developed and trained using CCTA image data from this large plurality of individuals. Ex. 56 (Cleerly Presents Late-Breaking Research, https://cleerlyhealth.com/press/research-on-ai-enabled-quantitative-ct-coronary-assessment). Upon information and belief, in the training process, Cleerly's convolutional neural network models performed coronary segmentation and labeling of

each individual's vasculature (i.e., determining a model of vascular geometry for each individual comprising one or more points) in order to generate the quantitative features used to train the algorithm. Ex. 60 (Cho et al., https://pmc.ncbi.nlm.nih.gov/articles/PMC9701371/).

193. At least Claim 1 also requires determining, for each individual's model, a selected point corresponding to the selected location in the patient's vascular system; determining, for each selected point of each individual's model, an individual-specific numerical description of one or more factors that affect cardiac risk. Cleerly's AI platform extracts quantitative features from each individual's CCTA data at points throughout the coronary vasculature, including plaque volumes categorized by type (non-calcified plaque, low-density non-calcified plaque, and calcified plaque using standard HU thresholds), stenosis measurements (maximum stenosis diameter percentage), lumen volume, total plaque burden, and vascular remodeling index. Ex. 60 (Cho et al., https://pmc.ncbi.nlm.nih.gov/articles/PMC9701371/).

194. These are available visually and quantitatively along various points and segments of each vessel. For example, in the CONFIRM2 global multicenter study involving 3,551 symptomatic patients across 18 sites and 13 countries, Cleerly's AI-QCT analysis extracted quantitative atherosclerotic features on a per-point, per-lesion, and per-vessel basis and identified that "% Diameter Stenosis and Non-Calcified Plaque Volume" were the strongest predictors of major adverse cardiovascular events (MACE). Ex. 56 (Cleerly Presents Late-Breaking Research, https://cleerlyhealth.com/press/research-on-ai-enabled-quantitative-ct-coronary-assessment). Each of these quantitative features constitutes an individual-specific numerical description of one or more factors that affect cardiac risk.

195. At least Claim 1 also requires generating, for the selected location of the patient's vascular system, a patient-specific numerical description of one or more factors that affect cardiac

risk based on each of the individual-specific numerical descriptions. Upon information and belief, for each patient analyzed, Cleerly generates a set of quantitative measurements at each lesion location, including plaque volume, plaque composition (non-calcified, low-density non-calcified, and calcified plaque), stenosis severity (both diameter and area), positive remodeling, low attenuation plaque volume, lumen volume, vessel volume, and percentage atheroma volume (PAV)—all derived from the AI models trained on the individual-specific numerical descriptions from the plurality of individuals described above. Ex. 41 (https://cleerlyhealth.com/what-is-cleerly); Ex. 62 (Nurmohamed et al., https://www.jacc.org/doi/10.1016/j.jcmg.2023.05.020). These patient-specific measurements are presented in "a comprehensive report to support providers in efficient diagnosis and personalized patient treatment" and are viewable through Cleerly's "interactive web platform." Ex. 41 (https://cleerlyhealth.com/what-is-cleerly).

196. At least Claim 1 also requires predicting a cardiac risk of the patient based on (i) the determined coronary plaque vulnerability present at the location in the patient's vascular system and (ii) the patient-specific numerical description. Cleerly's AI platform integrates both plaque vulnerability assessments and quantitative numerical descriptions to predict cardiac risk. Specifically, Cleerly's Plaque Analysis product provides various plaque volumes and measures that have been shown to predict "long-term cardiovascular outcomes," and Cleerly's published staging of quantitative plaque burden metrics (patient-specific numerical descriptions). Ex. 62 (Nurmohamed et al., https://www.jacc.org/doi/10.1016/j.jcmg.2023.05.020). For example, Cleerly's comprehensive AI-based analysis demonstrated that these quantitative features are compared to "traditional clinical risk scores" for predicting MACE, confirming that Cleerly's platform predicts cardiac risk based on both plaque vulnerability and patient-specific numerical descriptions. Ex. 56 (Cleerly Presents Late-Breaking Research,

https://cleerlyhealth.com/press/research-on-ai-enabled-quantitative-ct-coronary-assessment). Cleerly's analysis "included percent atheroma volume (PAV), low-density non-calcified-plaque (LD-NCP), non-calcified-plaque (NCP), calcified-plaque (CP), length, and high-risk-plaque (HRP), defined by LD-NCP and positive arterial remodeling >1.10 (PR)." Ex. 68 (Cho et al., Quantitative plaque analysis with A.I.-augmented CCTA in end-stage renal disease and complex CAD, https://pubmed.ncbi.nlm.nih.gov/35835019/).

197. Accused '303 Cleerly Product "demonstrate[d] elevated plaque burden and stenosis caused by predominantly non-calcified-plaque. Furthermore, the quantity of calcified-plaques increased with age, with men exhibiting increased number of 2-feature plaques and higher plaque volumes. Artificial-intelligence augmented CCTA analysis of APCs may be a promising metric for cardiac risk stratification" https://www.sciencedirect.com/science/article/pii/S0899707122001681.

198. Cleerly's updated reports include "detailed information about each lesion" and "lesion-specific data" that providers use "to assess a patient's risk for a heart attack and offer personalized treatment recommendations." Ex. 41 (https://cleerlyhealth.com/what-is-cleerly); Ex. 35 (https://cleerlyhealth.com/patient-education). Non-calcified plaque is a high-risk plaque, which is the plaque vulnerability, and the Accused '303 Cleerly Product provides a patient specific number for total non-calcified plaque. "By identifying high-risk plaque features, particularly large non-calcified lesions, we can now detect vulnerable patients who would have been missed by conventional stenosis-focused evaluations." https://cleerlyhealth.com/press/tct-2025-late-breaking-science .

199. Additional evidence of the Accused '303 Cleerly Product infringing Claims 1, 3-5, 7, 9, 11-13, 15, 17, 19, and 20 is included in the documents below, including representations

Cleerly made in its FDA filings and details Cleerly disclosed about techniques it implements regarding plaque vulnerability in the Accused '303 Cleerly Product in articles and appendices attached to the articles.

200. For example, an FDA submission dated September 22, 2020 includes representations by Cleerly that provide evidence of the Accused '303 Cleerly Product infringing one or more claims of the '303 Patent, including "determining the presence and extent of coronary plaques and stenosis":

Cleerly Labs is a web-based software application that is intended to be used by trained medical professionals as an interactive tool for viewing and analyzing cardiac computed tomography (CT) data for determining the presence and extent of coronary plaques (i.e., atherosclerosis) and stenosis in patients who underwent Coronary Computed Tomography Angiography (CCTA) for evaluation of CAD or suspected CAD. This software post processes CT images obtained using any Computed Tomography (CT) scanner. The software provides tools for the measurement and visualization of coronary arteries.

Cleerly 510(k) Summary, K202280, September 22, 2020 (Ex. 47)

4. Device Description

Cleerly Labs is a post-processing web-based software application that enables trained medical professionals to analyze 2D/3D coronary images acquired from Coronary Computed Tomography Angiography (CCTA) scans. The software is a post-processing tool that aids in determining treatment paths for patients suspected to have coronary artery disease (CAD).

Cleerly Labs utilizes machine learning and simple rule-based mathematical calculation components which are performed on the backend of the software. The software applies deep learning methodology to identify high quality images, segment and label coronary arteries, and segment lumen and vessel walls. 2D and 3D images are presented to the user for review and manual editing. This segmentation is designed to improve efficiency for the user, and help shorten tedious, time-consuming manual tasks.

Cleerly Labs provides a visualization of the Cleerly Labs analysis in the CORONARY Report. The CORONARY Report uses data previously acquired from the Cleerly Labs image analysis to generate a visually interactive and comprehensive report that details the atherosclerosis and stenosis findings of the patient. This report is not intended to be the final report (i.e., physician report) used in patient diagnosis and treatment. Cleerly Labs provides the ability to send the text report page of the CORONARY Report to the user's PACS system.

Id.

6. Software Functionality

In Cleerly Labs, users can edit the lumen and vessel walls of the suggested segmentation, and demarcate stenosis and stents, to more efficiently perform coronary analysis. Users are provided with navigation and editing/visualization tools to aid in image analysis. Plaque (i.e., atherosclerosis) and stenosis measurements are outputted based on the fully user-editable segmentation of the coronary artery. The user is also provided with the ability to indicate coronary anatomical findings.

Following the completion of study analysis, an interactive CORONARY Report is generated (the subject device of this submission). The CORONARY Report summarizes the analysis data from Cleerly Labs by reporting them as findings on atherosclerosis and stenosis, which may be used as supporting data in the evaluation of CAD. Components of the CORONARY Report include data visualization and reporting features. **Table 4** below compares the key features of the subject and predicate devices.

Id.

201. An additional FDA submission dated October 9, 2019 includes representations by Cleerly that also provide evidence of the Accused '303 Cleerly Product infringing one or more claims of the '303 Patent:

Device Description

Cleerly Labs is a post-processing web-based software application that enables trained medical professionals to analyze 2D/3D coronary images acquired from Computed Tomography (CT) angiographic scans. The software is a post-processing tool that aids in determining treatment paths for patients suspected to have coronary artery disease (CAD).

The output of the software includes visual images of coronary arteries, distance and volume measurements of the lumen wall, vessel wall, and plaque, remodeling index as well as stenosis diameter and area. These measurements are based on user segmentation.

Cleerly 510(k) Summary, K190868, October 9, 2019 (Ex. 48)

- A Usability test was conducted with U.S. board certified radiologists and technicians to ensure the clinical acceptability of the device.
- The machine learning algorithms were evaluated by comparing the output of the software to that of the ground truth using multiple ground truthers.

Id.

Visualization / Edit Tools	• Lumen Wall • Vessel Wall • Segment • Stenosis • Centerline • Plaque • Chronic Total Occlusion (CTO) • Stent • Exclude • Distance
2D Imaging	Yes
3D Imaging	Yes
Multiplanar Reformat (MPR)	Yes
Segmentation of region of interest	Manual and Semi-Automatic

Quantification	
Hounsfield Unit (HU)	Yes
Distance Measurements	• Vessel • Lesion • Length
Volumetric Measurements	• Total Vessel • Total Lumen • Non-Calcified Plaque (NCP) • Low-Density Non-Calcified Plaque (LD-NCP) • Calcified Plaque (CP) • Total Plaque
Remodeling Index	Yes
Stenosis	• % Area Stenosis • % Diameter Stenosis

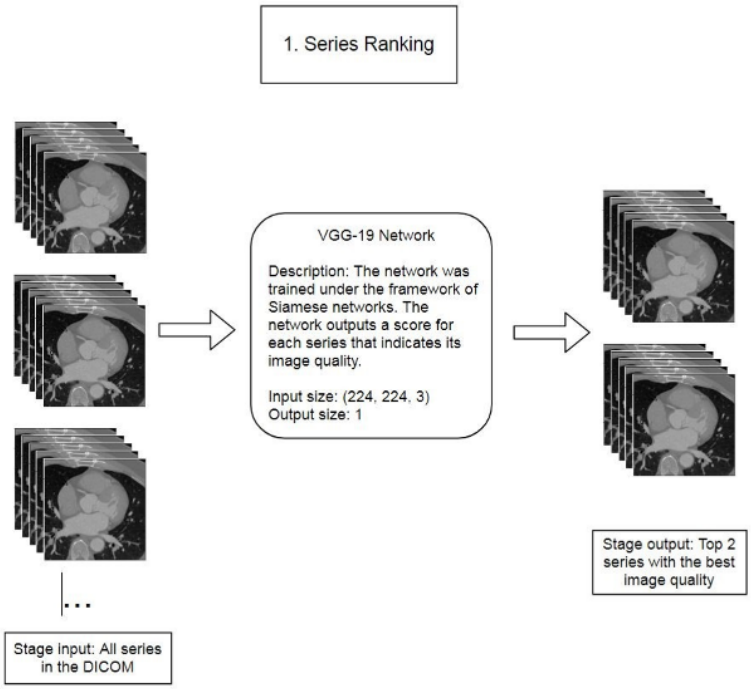
Id.

202. Further, upon information and belief, the following publication provides evidence of specific techniques implemented by the Accused '303 Cleerly Product, including plaque characterization and quantifying plaque, providing "scores," generating 3D models, identifying dimensions, plaque quantification, and/or additional features demonstrating that the Accused '303 Cleerly Product infringes one or more claims of the '303 Patent:

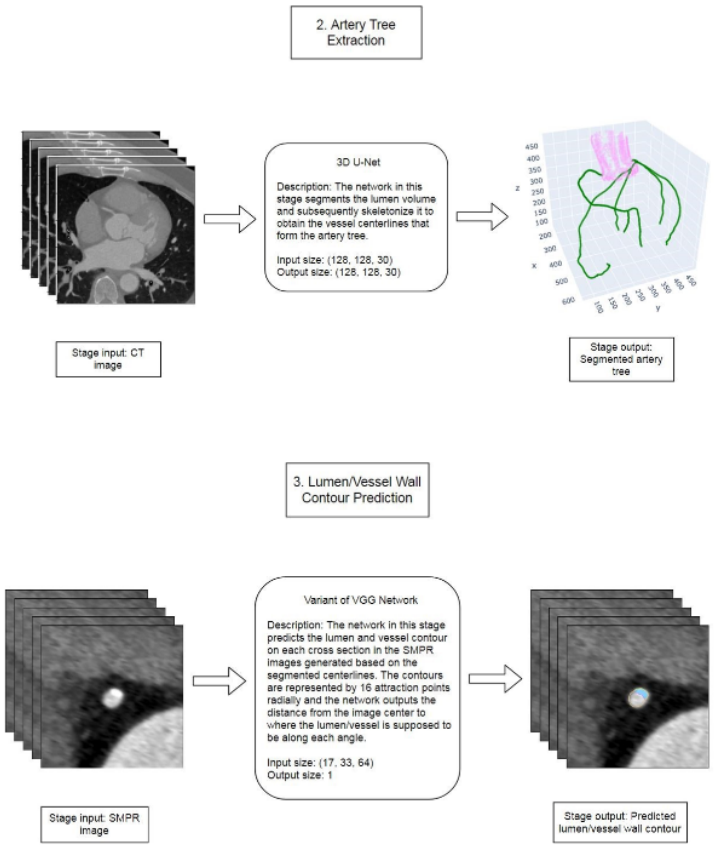
Appendix B: Artificial Intelligence/Machine Learning Steps to CCTA Image Evaluation: The following figures present in graphical detail the stepwise use of artificial intelligence algorithms used for CCTA analysis.

This is an AI-aided approach (Cleerly Inc, New York, NY) that performs an automated analysis of CCTA using a series of validated convolutional neural network models (including VGG 19 network, 3D U-Net and VGG Network Variant) for image quality assessment, coronary segmentation and labeling, lumen wall evaluation and vessel contour determination and plaque characterization(19). No manual interaction is required from the reader. First, the AI-aided approach leverages 2 deep convolutional neural networks (VGG-19 Network and 3D U-Net) to produce a centerline along the length of the vessel, and then for lumen and outer vessel wall contouring. This approach is applied to multiple phases/series of the CCTA examination, if present, and enables phase-specific evaluation at the coronary segment vessel. The algorithm reviewed all series and determined the top 2 optimal series for further analysis including vessel and lumen segmentation, plaque, and stenosis quantification. The algorithm rank-orders all available phases for the segmentation of the arteries. It then uses the top two phases interactively on a per vessel basis, e.g., the right coronary artery (RCA) will be reconstructed from the phase which yields the highest RCA image quality, while the posterior descending artery (PDA) may come from the second phase if the PDA has a higher image quality on that phase. Once coronary artery segmentation is performed, an automated labeling is done to classify arteries by their location as well the proximal, mid and distal portions within a single vessel. The AI further allows for defining of coronary artery lesions (i.e., those areas where plaque is present; VGG Network Variant). Utilizing a normal proximal reference vessel cross-sectional slide, the start and the end of the lesion, and the cross-sectional slice that demonstrates the greatest absolute narrowing, % diameter stenosis severity is automatically calculated. The software determines the start and end of lesions and drops stenosis markers at the region of the highest stenosis. Within coronary artery lesions, plaque is quantified in a similar fashion, and further characterized as low-attenuation non-calcified plaque, non-calcified plaque and calcified plaque based upon Hounsfield unit (HU) densities of <30, -189 to 350, >350, respectively. Positive arterial remodeling was identified as a remodeling index ≥1.10 by diameter when compared to a proximal vessel reference. Vessel length, vessel volume, lumen volume, total plaque volume, calcified plaque volume, noncalcified plaque volume, low density noncalcified plaque volume, maximum diameter and area stenosis, and maximum remodeling index are calculated.

Choi AD, et al. CT Evaluation of Coronary Artery Disease by AI: Appendix B (Ex. 49)



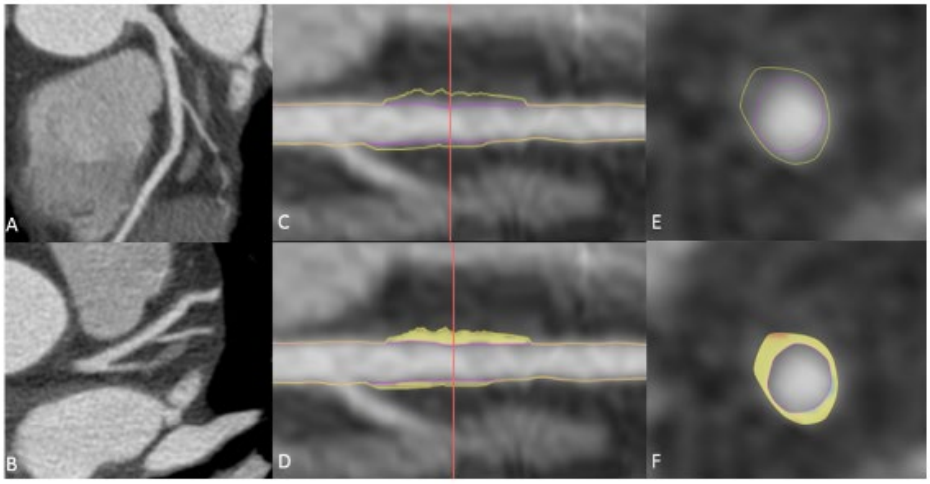
Id.



Id.

Supplement Figure 2: Contingency Tables of Level 3 Reader vs AI CAD-RADS Scores by CAD-RADS 0-3 and 4-5. These categories were chosen to represent a medical therapy (<70% stenosis) vs interventional (>70%) treatment threshold. On a per-vessel and per-patient basis, L3 and AI had 99.9% and 99.6% category agreement for these thresholds with weighted kappa values of 0.96 and 0.95 respectively.

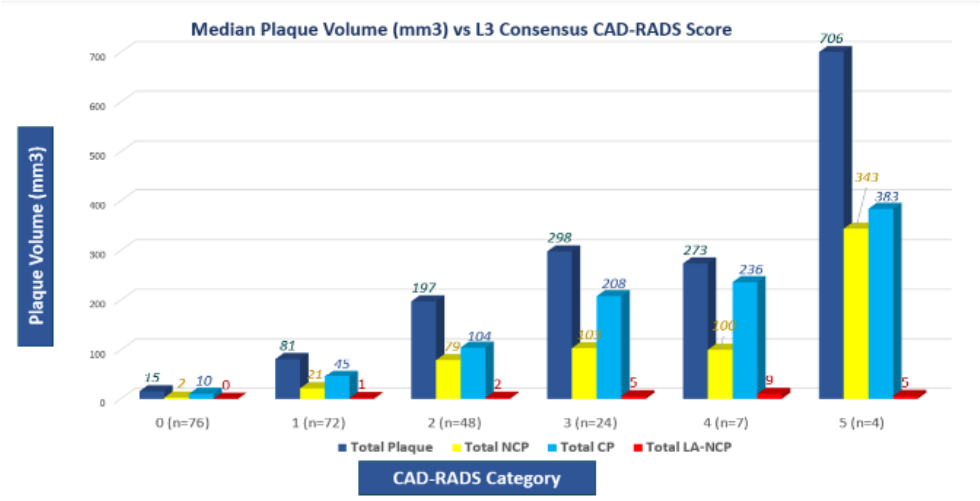
Choi AD, et al. CT Evaluation of Coronary Artery Disease by AI: Appendix A (Ex. 50)



Id.

Supplement Figure 3: Example case of discordance between AI and Level 3 Expert Consensus. The most common disagreement between expert consensus reads and AI reads was expert consensus CAD-RADS 0 and AI CAD-RADS 1. In this example of a 56-year-old male with dyspnea and a strong family history of CAD, the expert consensus read was a CAD-RADS 0 with no stenosis and no plaque (Panel A: Proximal and mid left anterior descending coronary artery curved multiplanar reformation [MPR]; Panel B: axial image of proximal and mid left anterior descending). The AI depicted 82 mm^3 of circumferential noncalcified plaque in the mid LAD with no coronary stenosis (Panel C: A straightened MPR depicting AI segmentation of the lumen boundary [purple line] and outer vessel wall [yellow line], Panel D: Same image as Panel C with a color overlay of noncalcified plaque (density >30 and < 350 HU), Panel E: A short axis MPR generated at the mid plaque level [red line] from image C again depicting lumen [purple] and vessel wall outer boundaries [yellow]; Panel F: Same as Panel E with color overlay of the noncalcified plaque [density >30 and < 350 HU]).

Id.



Supplemental Figure 4: **Median AI quantified plaque volume vs Level 3 Consensus by CAD-RADS Categorization**. Quantified plaque volume showed a broad range of values across CAD-RADS categories. NCP = Non-calcified plaque; CP = Calcified plaque; LA-NCP = Low attenuation non-calcified plaque

Id.

203. Further, upon information and belief, the functionality of the Accused '303 Cleerly Product is described in the paper titled "CT Evaluation by Artificial Intelligence for Atherosclerosis, Stenosis and Vascular Morphology (CLARIFY): A Multi-center, international study" (Ex. 51), which also provides additional evidence that the Accused '303 Cleerly Product infringes one or more claims of the '303 Patent:

Artificial Intelligence Segmentation and Plaque Quantification. CCTA studies were uploaded to and analyzed by FDA-cleared software Cleerly LABS (Cleerly, New York, New York).[17,18] The three sites contributing cases were not used for software development or validation. This study is an investigator initiated study and Cleerly had no role in the study design or performance. Cleerly performed AI-aided CCTA analyses for the study in a blinded manner, and provided statistical services as determined and requested by study investigators.

This is an AI-aided approach (**Central Illustration**) that performs automated analysis of CCTA using a series of validated convolutional neural network models (including VGG 19 network, 3D U-Net and VGG Network Variant) for image quality assessment, coronary segmentation and labeling, lumen wall evaluation and vessel contour determination and plaque characterization.[10,19] A full graphical representation of the algorithm with validation details is presented in Appendix B. First, the AI-aided approach leverages 2 deep convolutional neural networks to *Id.*

quantification. The algorithm rank-orders all available phases for the segmentation of the arteries. It then uses the top two phases interactively on a per vessel basis, e.g., the right coronary artery (RCA) will be reconstructed from the phase which yields the highest RCA image quality, while the posterior descending artery (PDA) may come from the second phase if the PDA has a higher image quality on that phase. Once coronary artery segmentation is performed, an automated labeling is done to classify arteries by their location as well the proximal, mid and distal portions within a single vessel. The AI further allows for defining of coronary artery lesions (i.e., those areas where plaque is present). Utilizing a normal proximal reference vessel cross-sectional slide, the start and the end of the lesion, and the cross-sectional slice that demonstrates the greatest absolute narrowing, % diameter stenosis severity is automatically calculated. The software determines the start and end of lesions and drops stenosis markers at the region of the highest stenosis. Within coronary artery lesions, plaque is quantified in a similar fashion, and further characterized as low-attenuation non-calcified plaque, non-calcified plaque and calcified plaque based upon Hounsfield unit (HU) densities of <30, -189 to 350, >350, respectively. Positive arterial remodeling was identified as a remodeling index ≥ 1.10 by diameter when compared to a proximal vessel reference. We used a coronary ar-

Id.

L3 readers determined maximum diameter stenosis was compared with AI stenosis on a per-patient and per-vessel basis. Correlation and numeric agreement were assessed. The Pearson correlation coefficient was used to evaluate correlation, linear regression plots were generated for visualization of the relationship. Bland-Altman plots with limits of agreement was performed. Diagnostic performance of AI vs L3 was assessed through diagnostic accuracy, sensitivity, specificity, positive and negative predictive values at both >50% and >70% stenosis thresholds on per vessel and per patient basis.

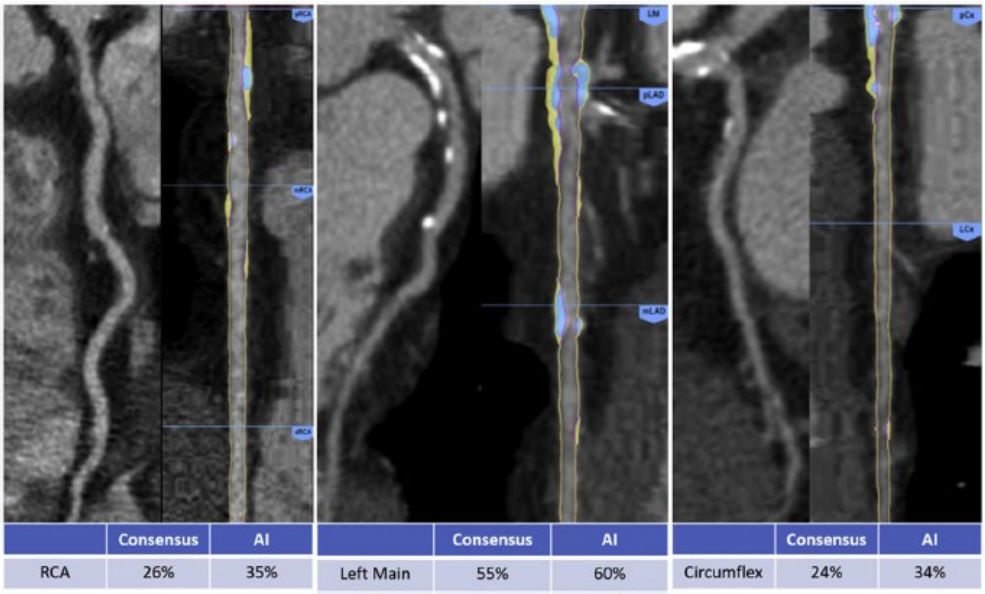
Id.

Readers determined presence of two high risk plaque features—low attenuation plaque <30 Hounsfield units (HU) and positive arterial remodeling with a remodeling index ≥1.10 by diameter—with this analysis compared with AI on per vessel and per patient basis. This binary outcome was compared by calculating the percent agreement and kappa statistic.

Id.

CAD-RADS Categorization. Fig. 1 depicts consensus reads versus AI results. Overall, 182/232 (78.0%) had CAD-RADS categorical agreement, 228/232(98.3%) agreed within one category. The most frequent disagreement occurred with expert consensus CAD-RADS 0 and AI CAD-RADS 1 (n = 29 12.5% per patient, n = 161 17.4% per vessel). To further evaluate L3 consensus vs AI for a collated mild-moderate versus severe stenosis categories, at a threshold for potential interventional treatment (>70% stenosis), we evaluated CAD-RADS 0–3 and CAD-RADS 4–5 to assess accuracy and found only 1 case of discrepancy on either a per-

Id.



	Consensus	AI
RCA	26%	35%

	Consensus	AI
Left Main	55%	60%
LAD	53%	47%

	Consensus	AI
Circumflex	24%	34%

Id.

Fig. 2. Example Case of Consensus Between Artificial Intelligence and Level 3. Example of a study depicting excellent agreement between maximal percent diameter stenosis in a 53-year-old make with exertional chest pain. On the left readers using a curved multiplanar reformat (cMPR) of the RCA determined a consensus stenosis of 26%, the straightened MPR to its right with colored plaque overlay (in blue and yellow) generated by AI found 35% maximal stenosis. In the middle the cMPR used by readers determined 55% stenosis of the left main and 53% of the LAD, AI to its right with colored plaque overlay (in blue and yellow) by AI found 53 and 47% respectively. On the right the cMPR used by readers determined 24% stenosis of the left circumflex, AI with colored plaque overlay (in blue and yellow) by AI determined 34%. (For interpretation of the references to color in this figure legend, the reader is referred to the Web version of this article.)

Machine Learning Applied to CCTA. Recent studies have begun to evaluate individual aspects of AI-enabled plaque quantification, though few of these solutions are currently available clinically. Zreik et al. used a multitask recurrent convolutional neural network in n = 166 for automatic characterization of plaque.[38] They achieved a linearly weighted kappa of 0.68, 0.66 and 0.67 at the segment, artery and patient-level for the binary presence or absence of non-calcified, mixed and calcified plaque. Kang et al. used a support vector machine (SVM) learning algorithms in a small number of datasets (n = 42) for detection of plaque for lesions a simplistic severity of ≥25% in comparison to experienced expert consensus readers and reported accuracy of 94%.[39]

Id.

204. The foregoing features and capabilities of each of the Accused '303 Cleerly Product description and/or demonstration thereof, including in advertising, reflect Cleerly's direct infringement by satisfying every element of at least Claims 1, 3-5, 7, 9, 11-13, 15, 17, 19, and 20 of the '303 Patent under 35 U.S.C. § 271(a).

205. Upon information and belief, Cleerly has induced infringement, and continues to induce infringement, of one or more Claims 1, 3-5, 7, 9, 11-13, 15, 17, 19, and 20 of the '303 Patent by actively and knowingly inducing others, including health care providers and hospitals in the Eastern District of Texas and throughout the United States, to directly infringe one or more claims of the '303 Patent through the use of Cleerly's products and services. For example, Cleerly instructs hospital employees and doctors, and induces patients through its website, via generating tutorial videos for training purposes, training hospital employees, conducting webinars, conducting demos at events, and/or producing instructional videos to induce them to directly infringe one or more claims of the '303 Patent through the use of the Accused '303 Cleerly Product. *See* https://www.youtube.com/@cleerlyhealth/videos (Ex. 42); https://cleerlyhealth.com/clinical-

publications; https://cleerlyhealth.com/blog; https://cleerlyhealth.com/webinars; https://cleerlyhealth.com/events.

206. Upon information and belief, Cleerly has contributed to the infringement of one or more of Claims 1, 3-5, 7, 9, 11-13, 15, 17, 19, and 20 of the '303 Patent by providing products and services that constitute material parts of the claimed inventions, knowing the same to be especially made or adapted for use in an infringing manner. For example, the Accused '303 Cleerly Products include at least one component to generate images and implement plaque quantification to be used in conjunction with the Cleerly Platform to perform CAD detection. This is a component of a patented machine, manufacture, or combination, or an apparatus for use in practicing a patented process. Furthermore, such component is a material part of the invention and upon information and belief is not a staple article or commodity of commerce suitable for substantial non-infringing use. Thus, Cleerly is liable for infringement of the '303 Patent pursuant to 35 U.S.C. § 271(c).

207. Upon information and belief, Cleerly has been on notice of the '303 Patent at least since its issuance, and Cleerly's infringement of the '303 Patent has been and continues to be willful. For example, Cleerly, through its founder, Dr. James K. Min, had actual knowledge of Heartflow's patent portfolio through Dr. Min's role as a Heartflow consultant from 2012 to 2017, his execution of an NDA and Consulting Agreement with Heartflow, and his role as lead investigator on Heartflow's DeFACTO study. Dr. Min incorporated Cleerly on July 19, 2016 while still subject to the Consulting Agreement and its confidentiality, non-compete, and invention assignment obligations. Cleerly further acquired actual knowledge of Heartflow's patents through its hiring of Brent Ness, Heartflow's former Chief Commercial Officer, who was bound by confidentiality obligations under the Ness Agreement and Separation Agreement. Cleerly has

knowledge about the ’303 Patent based on Cleerly citing the ’303 Patent repeatedly in its own patents as seen below:

Heartflow’s Patent	**Cleerly Patent Citing Heartflow’s Patent**
US9770303B2	US10813612B2 US11094060B1 US11210786B2 US11861833B2 US11922627B2 US12144669B2 US12380560B2 US12440180B2

208. By the time of trial, Cleerly will thus have known and intended (since receiving such notice), that its continued actions would actively induce and contribute to actual infringement of one or more Claims 1, 3-5, 7, 9, 11-13, 15, 17, 19, and 20 of the ’303 Patent.

209. Despite this actual knowledge of Heartflow’s patents, Cleerly deliberately chose to develop and commercialize infringing products rather than seek a license of those patents.

210. Cleerly undertook and continues its infringing actions despite an objectively high likelihood that such activities infringed the ’303 Patent, which has been duly issued by the USPTO and is presumed valid. For example, Cleerly has been aware of an objectively high likelihood that its actions constituted, and continue to constitute, infringement of the ’303 Patent based on Dr. Min’s actual knowledge and Cleerly’s knowledge as shown on Cleerly’s own patents, and that the ’303 Patent is valid. On information and belief, Cleerly cannot reasonably, subjectively believe that its actions do not constitute infringement of the ’303 Patent, nor could it reasonably, subjectively believe that the patent is invalid. Despite that knowledge and subjective belief, and the objectively high likelihood that its actions constitute infringement, Cleerly has continued its infringing activities. As such, Cleerly willfully infringes the ’303 Patent.

211. Heartflow has been damaged by Cleerly's infringement of the '303 Patent and is entitled to recover damages adequate to compensate for such infringement pursuant to 35 U.S.C. § 284.

COUNT 4 – CLEERLY's INFRINGEMENT OF U.S. PATENT NO. 9,839,399

212. Heartflow incorporates all preceding paragraphs by reference.

213. U.S. Patent No. 9,839,399 ("the '399 Patent") was duly issued on December 12, 2017, and is titled "Systems and Methods for Numerically Evaluating Vasculature." A copy of the '399 Patent is attached as Exhibit 10.

214. Heartflow is the owner by assignment of the '399 Patent and possesses all rights under the '399 Patent, including the exclusive right to recover for past and future infringement.

215. The '399 Patent is directed to novel and inventive technology as discussed above in at least paragraphs 17-41 and 96-103 and incorporated by reference, including computerized systems and methods for noninvasively evaluating a patient's vasculature and, in particular, for automatically scoring the coronary arterial tree using patient-specific imaging and computational modeling. The claimed invention receives noninvasively obtained, patient-specific arterial image data; segments and models the patient's coronary anatomy; automatically analyzes the modeled coronary tree to determine multiple arterial characteristics; generates numerical measurements for those characteristics; assigns point values; and executes a computer-implemented algorithm to provide a cardiovascular score. *See* '399 Patent at Abstract, 4:25–5:10, 6:5–16:35.

216. The '399 Patent identifies problems in the prior art, including that noninvasive tests provided only indirect anatomical or physiological signals and typically do not provide a direct assessment of coronary lesions. The '399 Patent also describes that a need exists to provide more accurate data relating to coronary lesions, e.g., size, shape, location, functional significance and a

need exists to noninvasively evaluating the complexity and extent of disease in a patient's coronary vasculature.

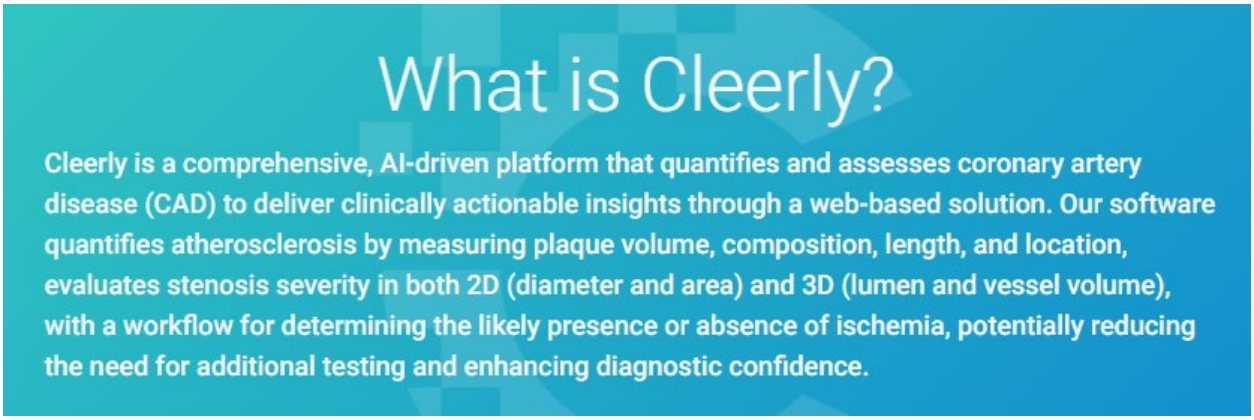
217. The '399 Patent discloses a solution that unifies these assessments in a noninvasive pipeline. The invention starts from patient-specific imaging, constructs a three-dimensional coronary model via automated segmentation, determines and evaluates multiple predefined arterial characteristics, assigns point values, and runs a computer-executed algorithm to generate a cardiovascular score. In certain embodiments, the invention produces a functional cardiovascular score by evaluating characteristics only for artery portions meeting a blood flow threshold, including FFR-based thresholds, such as 0.9, 0.8, or 0.7, and by using machine-learning comparisons to previously analyzed data to assist the evaluation.

218. The '399 Patent also contemplates normalizing or weighting the generated score to align with SYNTAX-style clinical decision thresholds, thereby delivering a reproducible, automated output that integrates both anatomical and functional information without resort to invasive measurement methods involving coronary catheters. The use of invasive techniques requires the probing of sensitive coronary arteries and vessels with flexible catheters that measure occlusion based on pressure sensors. As such, this requires the patient to undergo surgical anesthetic, and the creation of a wound. This procedure opens the patient to increased risk of complications involving a patient's reaction to anesthesia, operator/physician error, and the increased risk of infection at the catheter's insertion site.

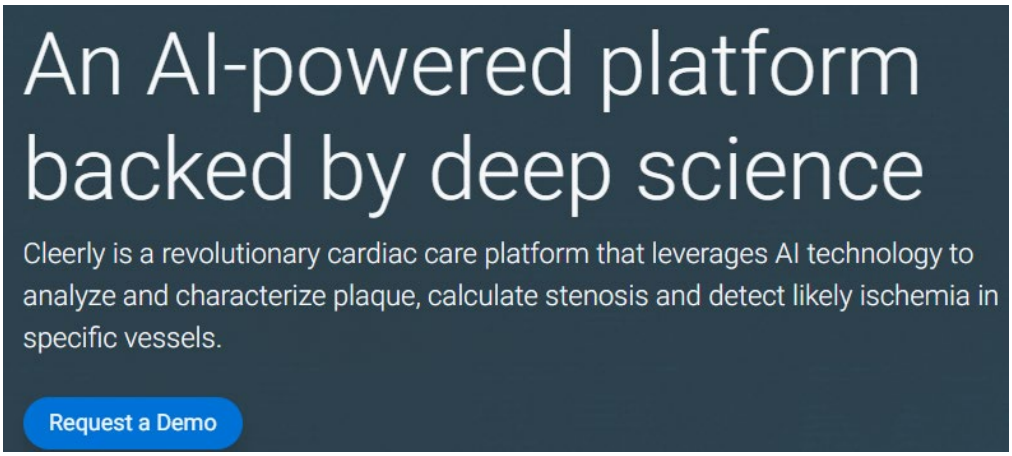
219. Evidence that the '399 Patent is valid and is directed to novel and inventive technology is discussed above in at least paragraphs 17-41 and 96-103 and incorporated by reference. Further, the '399 Patent has been recognized as a foundational patent as shown by the

fact that the '399 Patent family has been cited by over 105 additional patents, including patents filed by Cleerly, CathWorks, and Elucid Bioimaging.

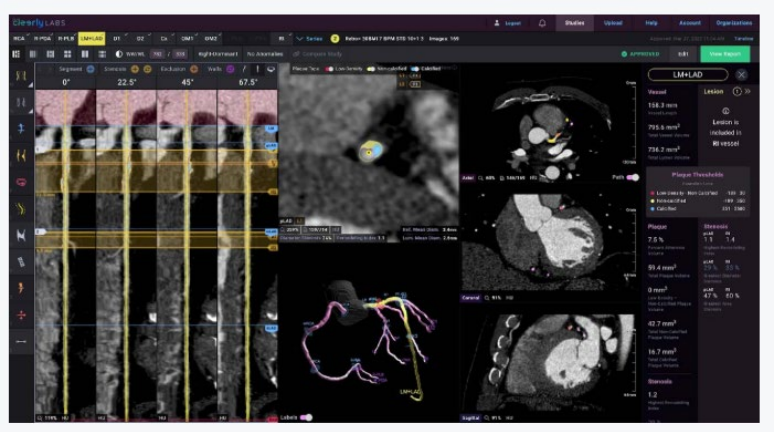
220. Upon information and belief, Cleerly has directly infringed, and continues to directly infringe, one or more claims of the '399 Patent in this District and elsewhere in Texas, including at least Claims 2-6, 8-14, and 17-18 literally and/or under the doctrine of equivalents, making, using, selling, offering to sell, and/or importing into the United States products and services that practice the inventions claimed therein, including, but not limited to, Cleerly Plaque Analysis and Cleerly ISCHEMIA (collectively, "the Accused '399 Cleerly Products"). For example, Cleerly provides a "comprehensive, AI-driven platform that quantifies and assesses coronary artery disease (CAD)" that "quantifies atherosclerosis by measuring plaque volume, composition, length, and location, evaluates stenosis severity in both 2D (diameter and area) and 3D (lumen and vessel volume), with a workflow for determining the likely presence or absence of ischemia." https://cleerlyhealth.com/ (Ex. 29).



https://cleerlyhealth.com/ (Ex. 29)



https://cleerlyhealth.com/what-is-cleerly (Ex. 41)



https://cleerlyhealth.com/what-is-cleerly (Ex. 41)

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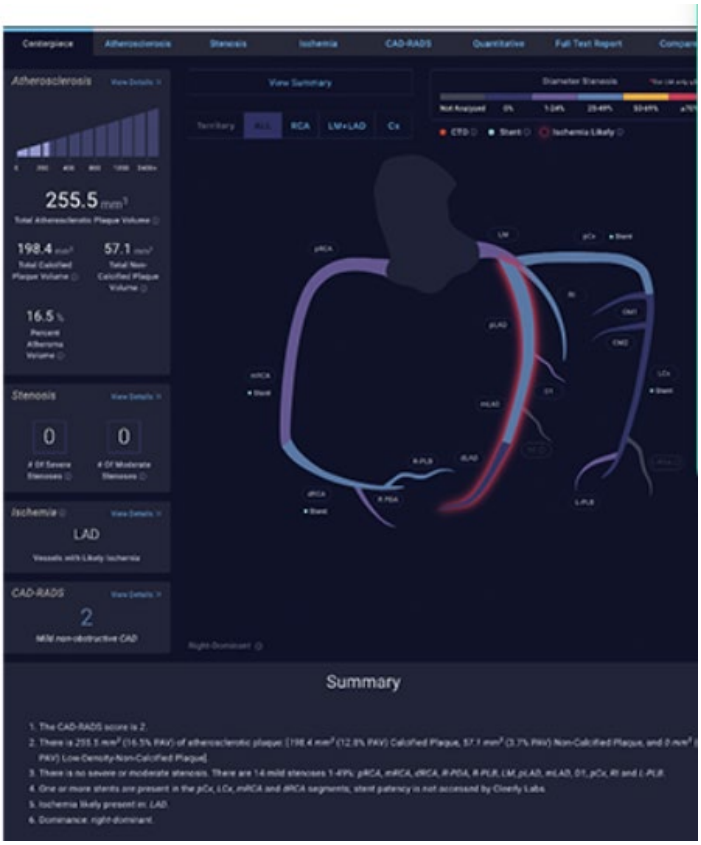
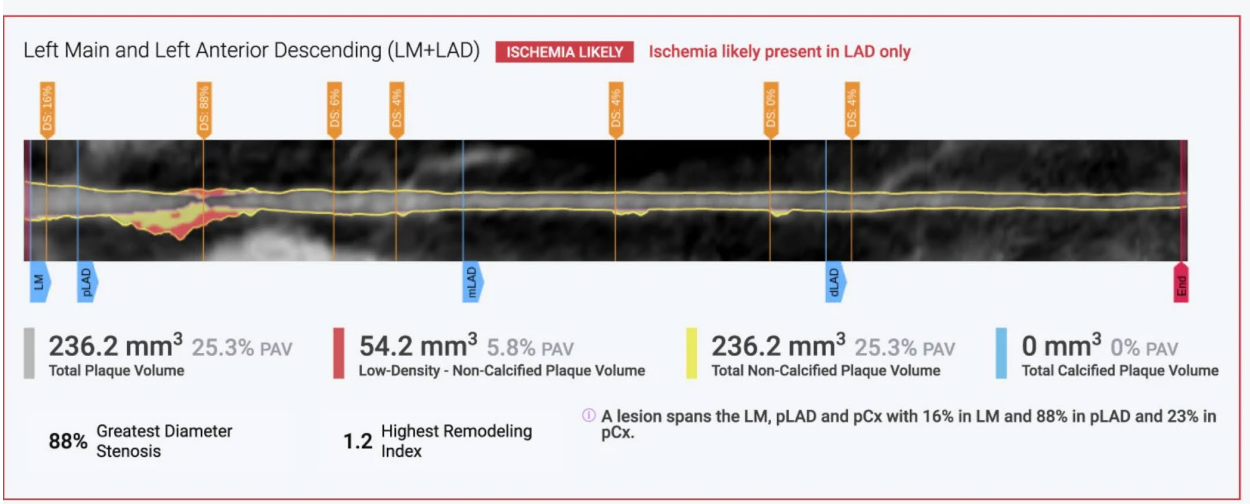


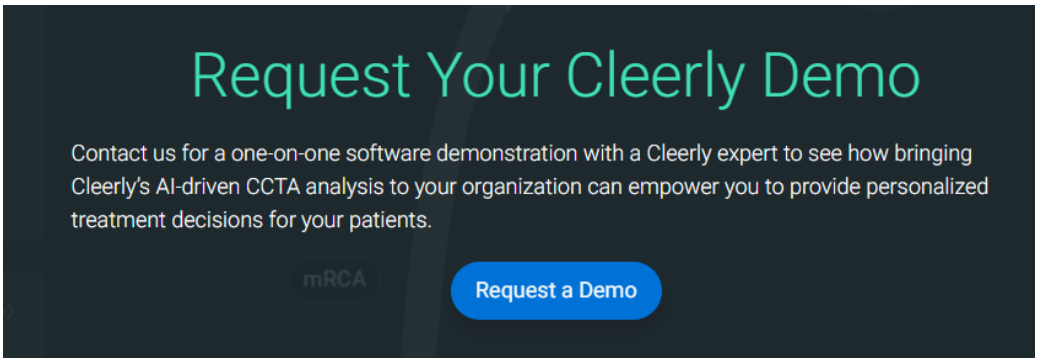
https://cleerlyhealth.com/what-is-cleerly (Ex. 41)



https://cleerlyhealth.com/patient-education (Ex. 35)

221. Heartflow reserves the right to discover and pursue any additional infringing products and services that incorporate infringing functionalities. For the avoidance of doubt, the Accused '399 Cleerly Products are identified to describe Cleerly's infringement and in no way limit the discovery and infringement allegations against Cleerly concerning other products that incorporate the same or reasonably similar functionalities.

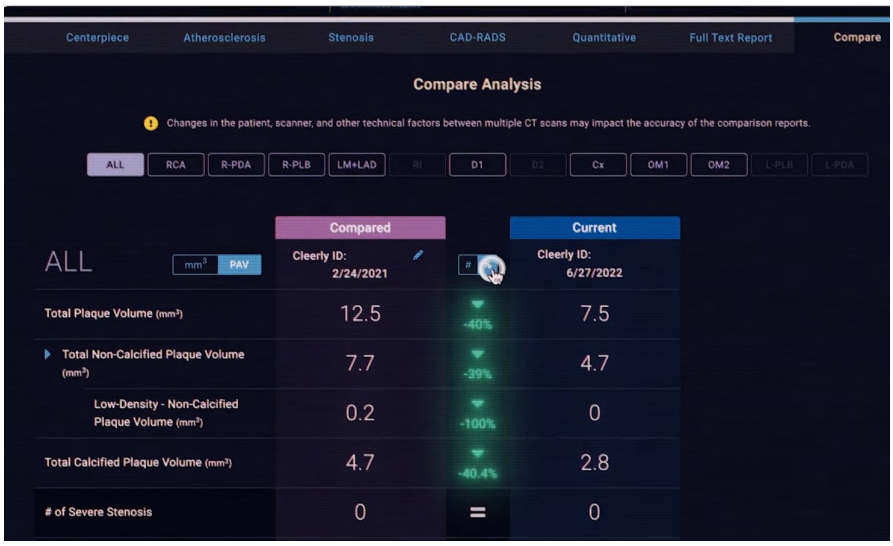
222. Upon information and belief, Cleerly directly infringes by performing one or more method claims in the United States when, for example, performing testing, including "usability tests" as confirmed in FDA submissions, generating tutorial videos for training purposes, training hospital employees, conducting webinars, conducting demos at events, and/or producing instructional videos showing how the Accused '399 Cleerly Products operate. https://www.youtube.com/@cleerlyhealth/videos (Ex. 42); https://cleerlyhealth.com/clinical-publications; https://cleerlyhealth.com/blog; https://cleerlyhealth.com/webinars; https://cleerlyhealth.com/events.



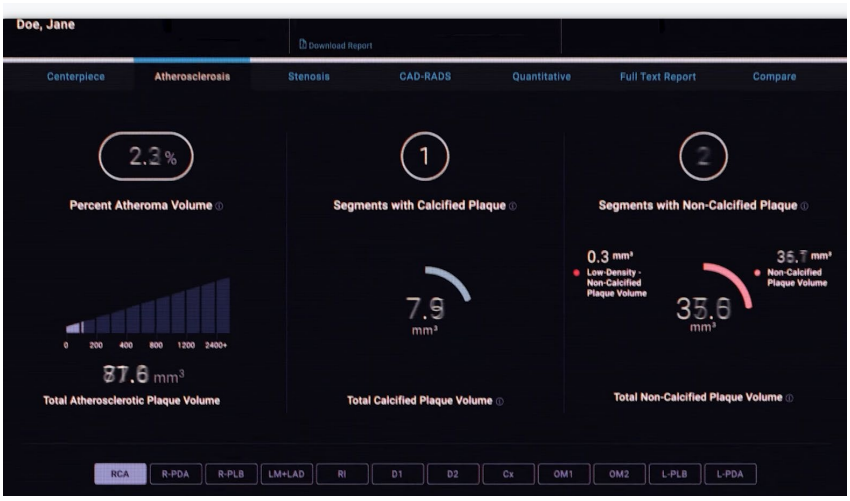
223. Each of the Accused '399 Cleerly Products, either alone or in combination with each other, perform a computer-implemented method for automatically generating a cardiovascular score for a patient from patient-specific data.

224. At least Claim 2 requires and the Accused '399 Cleerly Products receive noninvasively obtained, patient-specific coronary image data; create a model by automatically segmenting and labeling arterial geometric features; automatically analyze model-represented features to determine multiple characteristics; automatically characterize features by intensities, sizes, and/or topologies and compare them to thresholds; automatically evaluate each characteristic by generating numerical measurements; and automatically execute an algorithm using the assigned values to generate and provide a cardiovascular score presented within the Coronary Report and ISCHEMIA displays. *See* Ex. 52 (https://cleerlyhealth.com/plaque-analysis); Ex. 26 (Cleerly Non-Invasive Ischemia Analysis, https://cleerlyhealth.com/ischemia-reinvented); Ex. 48 (FDA 510(k) Premarket Notification K190868 (Cleerly Labs), https://www.accessdata.fda.gov/cdrh_docs/pdf19/K190868.pdf); Ex. 55 (FDA 510(k) Premarket Notification K231335 (Cleerly ISCHEMIA), https://www.accessdata.fda.gov/cdrh_docs/pdf23/K231335.pdf)

225. Upon information and belief, the Accused '399 Cleerly Products provide numerous scores:

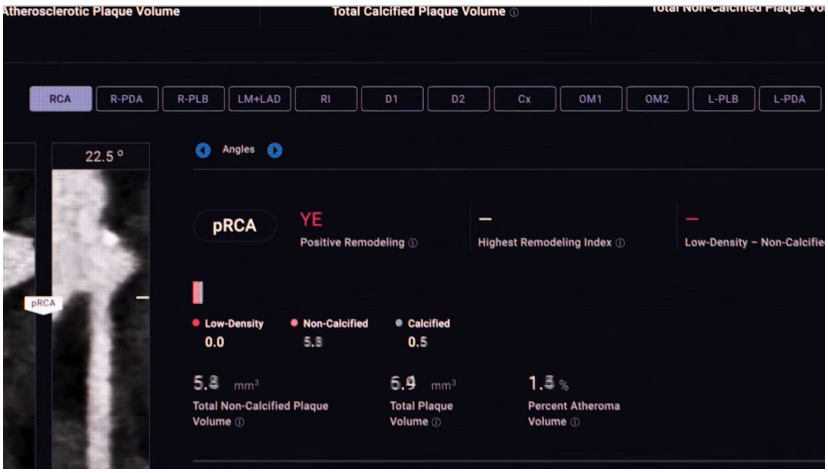


https://cleerlyhealth.com/ (Ex. 29)



https://cleerlyhealth.com/ (Ex. 29)

Id.



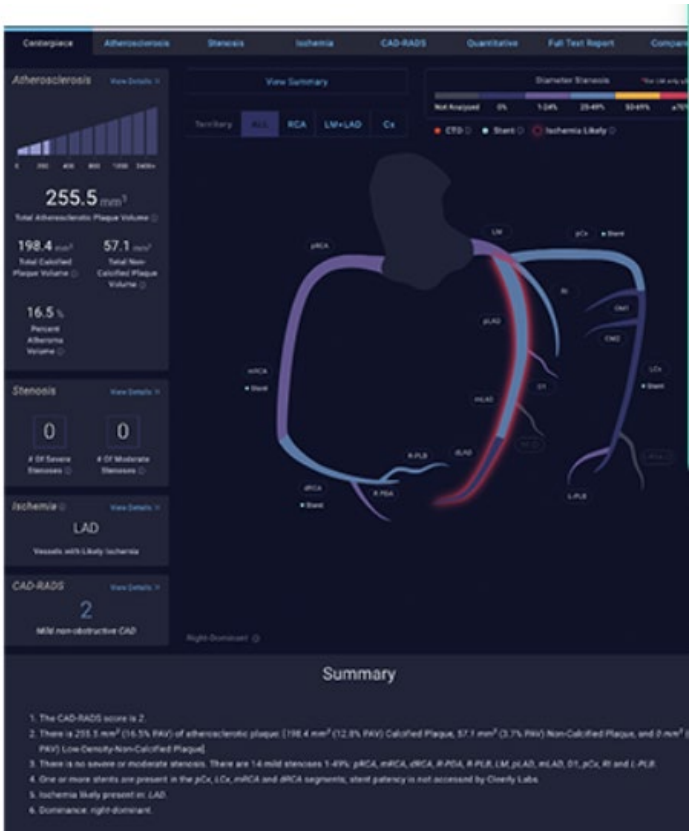
Id.

226. At least Claim 2 requires receiving non-invasively obtained patient-specific image data of one or more arteries of the patient. The Accused '399 Cleerly Products receive patient-specific data generated from a noninvasive imaging modality, including CCTA, as reflected in Cleerly's indications for use and user documentation. *See* Ex. 48 (FDA 510(k) Premarket Notification K190868 (Cleerly Labs), https://www.accessdata.fda.gov/cdrh_docs/pdf19/K190868.pdf) (intended use: post-processing of cardiac CT for coronary analysis); Ex. 57 (Cleerly Atherosclerosis, Stenosis and Ischemia Analysis, https://cleerlyhealth.com/diagnosing-cad).

> Cleerly uses proprietary and FDA-cleared machine learning algorithms to non-invasively measure atherosclerosis (plaque), stenosis, and likelihood of ischemia using coronary computed tomography angiography (CCTA) studies.
>
> Our machine-learning AI generates a 3D model of the patient's coronary arteries, identifies their lumen and vessel walls, locates and measures stenoses, while quantifying and categorizing plaque.[1] Cleerly ISCHEMIA's algorithm uses measurements based on invasive FFR data to determine the likelihood of vessel-level ischemia.[2]

https://cleerlyhealth.com/what-is-cleerly (Ex. 41)

227. At least Claim 2 also requires creating a model representing one or more geometric features of the one or more arteries of the patient by segmenting, using the at least one computer system, the one or more geometric features from the non-invasively obtained patient-specific image data. The Accused '399 Cleerly Products create such a model of a patient based on segmenting by relying on patient-specific data generated from a noninvasive imaging modality, including CCTA, as reflected in Cleerly's indications for use and user documentation. *See* Ex. 52 (https://cleerlyhealth.com/plaque-analysis); Ex. 26 (Cleerly Non-Invasive Ischemia Analysis, https://cleerlyhealth.com/ischemia-reinvented); Ex. 48 (FDA 510(k) Premarket Notification K190868 (Cleerly Labs), https://www.accessdata.fda.gov/cdrh_docs/pdf19/K190868.pdf); Ex. 55 (FDA 510(k) Premarket Notification K231335 (Cleerly ISCHEMIA), https://www.accessdata.fda.gov/cdrh_docs/pdf23/K231335.pdf)



https://cleerlyhealth.com/what-is-cleerly (Ex. 41)

Device Description

Cleerly Labs is a post-processing web-based software application that enables trained medical professionals to analyze 2D/3D coronary images acquired from Computed Tomography (CT) angiographic scans. The software is a post-processing tool that aids in determining treatment paths for patients suspected to have coronary artery disease (CAD).

The output of the software includes visual images of coronary arteries, distance and volume measurements of the lumen wall, vessel wall, and plaque, remodeling index as well as stenosis diameter and area. These measurements are based on user segmentation.

Cleerly 510(k) Summary, K190868, October 9, 2019 (Ex. 48)

- A Usability test was conducted with U.S. board certified radiologists and technicians to ensure the clinical acceptability of the device.
- The machine learning algorithms were evaluated by comparing the output of the software to that of the ground truth using multiple ground truthers.

Id.

Cleerly advanced coronary plaque analysis

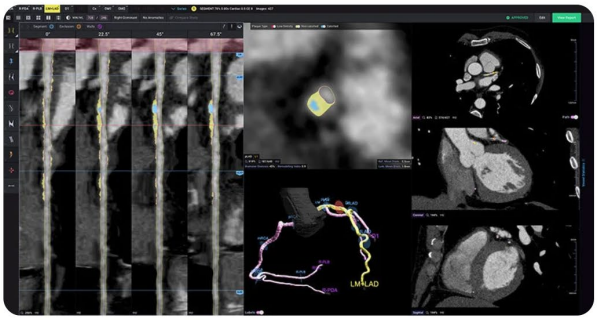
Predicting cardiovascular risk with AI precision

Vessel-by-vessel detail
Precision phenotyping for each artery and branch with stenosis quantification and vascular remodeling scores

Comprehensive plaque assessment
At-a-glance view of characterized plaque volume by coronary region

Stenosis scoring
Clear and concise summary of identified stenoses by severity

Supports next-gen hardware
Advanced segmentation on photon-counting CT



https://cleerlyhealth.com/plaque-analysis (Ex. 52)

4. Device Description

Cleerly ISCHEMIA is an add-on software module to Cleerly Labs (K202280, K190868) that determines the likely presence or absence of coronal vessel ischemia based on quantitative measures of atherosclerosis, stenosis, and significant vascular morphology from typically-acquired Coronary Computed Tomography Angiography images (CCTA). Cleerly ISCHEMIA, in conjunction with Cleerly Labs, outputs a Cleerly ISCHEMIA Index (CII), a binary indication of negative CII (likely absence of ischemia) or positive CII (likely presence of ischemia) with its threshold equivalent to invasive FFR >0.80 vs. ≤0.80, respectively, as identified in professional societal practice guidelines.

The Cleerly ISCHEMIA data workflow begins after the Cleerly Labs outputs are approved for a study. A pre-processing module evaluates the eligibility of a study or vessels within the study for the Cleerly ISCHEMIA algorithm. The presence of certain identified anomalies can make an entire study ineligible, whereas the presence of a stent or exclusion in a vessel can make just that vessel ineligible. For all eligible vessels within a study, relevant Cleerly Labs outputs are aggregated from the default segment level to vessel level as the inputs to the Cleerly ISCHEMIA algorithm to determine the likely presence of ischemia. The results will then be evaluated by a post-processing module, which ensures that vessels subtended to a likely ischemic vessel are also marked as likely ischemic. The Cleerly ISCHEMIA algorithm outputs a Cleerly ISCHEMIA Index (CII), a binary indication of likely ischemia presence vs absence for a given vessel, which is equivalent to invasive FFR ≤0.80 vs. >0.80, respectively. Invasive FFR is a widely accepted gold-standard for determining vessel-specific ischemia. The Cleerly ISCHEMIA algorithm is "locked," meaning it is not a continuous learning algorithm.

Cleerly ISCHEMIA Index (likely ischemia / not likely ischemia) is displayed visually by Cleerly Labs to show the likely presence or absence of ischemia within epicardial coronary artery vessels. Vessels with Cleerly ISCHEMIA Index indicating likely ischemia presence (positive CII) are illuminated red, while vessels with Cleerly ISCHEMIA Index indicating likely ischemia absence (negative CII) are not illuminated. Cleerly ISCHEMIA analysis is intended to non-invasively support the functional evaluation of clinically stable symptomatic patients with coronary artery disease (CAD).

https://www.accessdata.fda.gov/cdrh_docs/pdf23/K231335.pdf (Ex. 55)

228. At least Claim 2 also requires automatically analyzing the one or more geometric features represented in the model to determine multiple characteristics of the one or more arteries, wherein at least one of the multiple characteristics is selected from the group of left/right dominance, a total occlusion, a presence of an ostial disease, a tortuosity value, a length of a diseased vessel segment, one or more dimensions of calcified plaque, a thrombus, and a presence of a diffuse disease, and wherein automatically analyzing the one or more geometric features.

229. The Accused '399 Cleerly Products analyze the one or more geometric features represented in the model to determine multiple characteristics of the one or more arteries selected from a group of different characteristics. *See* Ex. 52 (https://cleerlyhealth.com/plaque-analysis); (Ex. 48) FDA 510(k) Premarket Notification K190868 (Cleerly Labs), https://www.accessdata.fda.gov/cdrh_docs/pdf19/K190868.pdf); Ex. 55.

Device Description

Cleerly Labs is a post-processing web-based software application that enables trained medical professionals to analyze 2D/3D coronary images acquired from Computed Tomography (CT) angiographic scans. The software is a post-processing tool that aids in determining treatment paths for patients suspected to have coronary artery disease (CAD).

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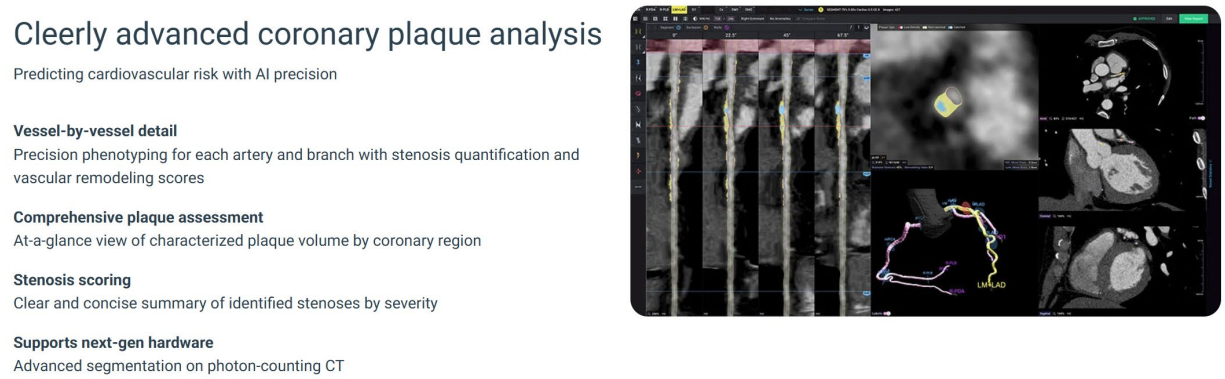
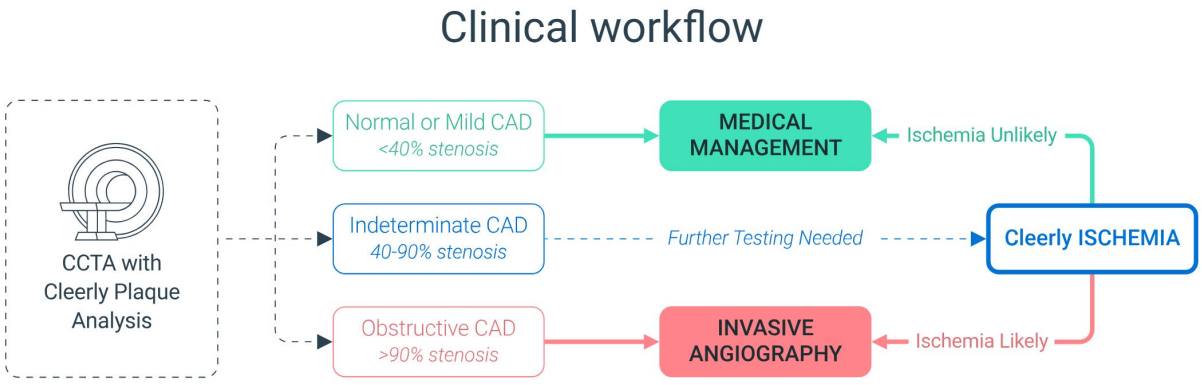
Cleerly 510(k) Summary, K190868, October 9, 2019 (Ex. 48)

- A Usability test was conducted with U.S. board certified radiologists and technicians to ensure the clinical acceptability of the device.
- The machine learning algorithms were evaluated by comparing the output of the software to that of the ground truth using multiple ground truthers.

Id.

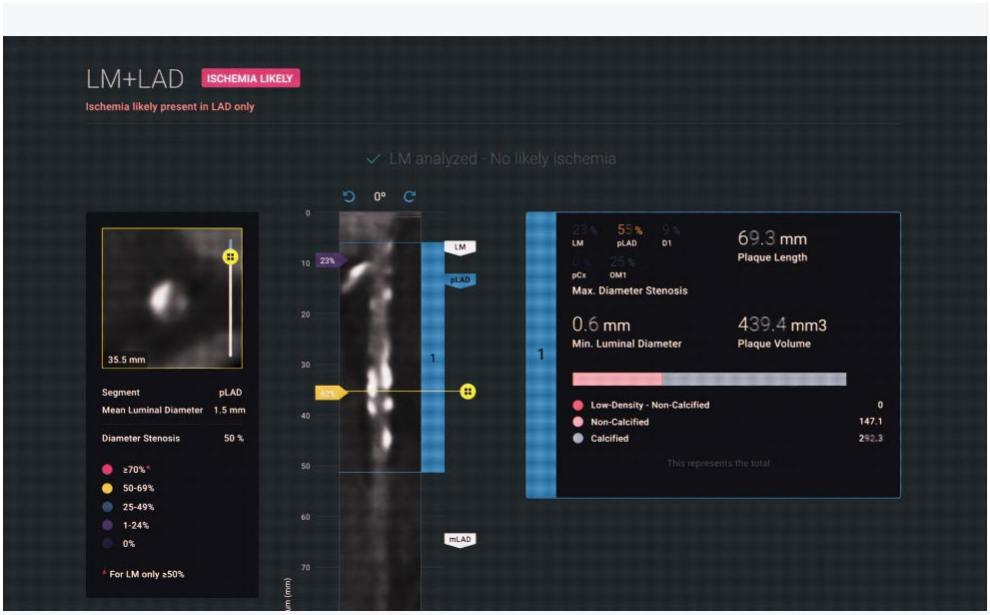


https://cleerlyhealth.com/plaque-analysis (Ex. 52)

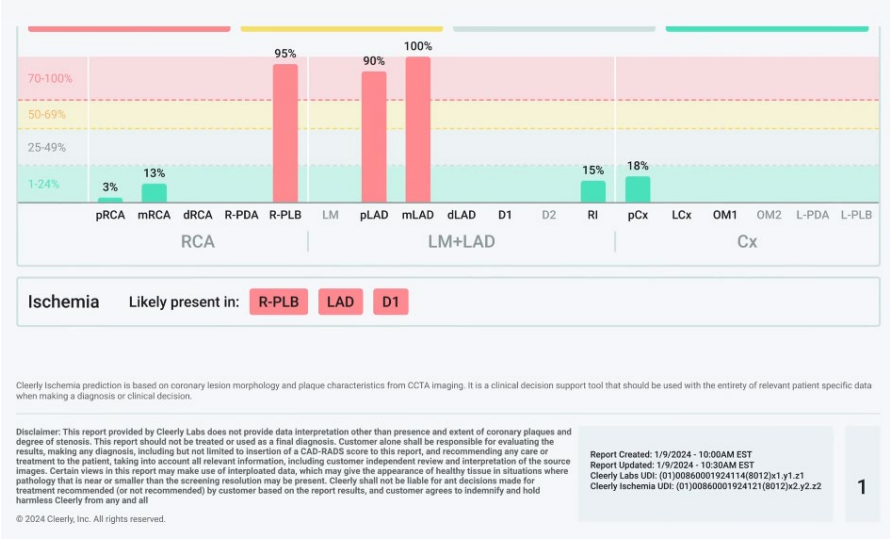


Ex. 26 (Cleerly Non-Invasive Ischemia Analysis, https://cleerlyhealth.com/ischemia-reinvented)

Cleerly ISCHEMIA is a first-of-its-kind, FDA-cleared heart disease evaluation that uses 37 measures of heart health to determine likelihood of coronary artery ischemia at a per-vessel level. Cleerly ISCHEMIA uses machine learning and concise reporting to aid physicians in personalizing patient treatment, including the planning of interventional treatments such as stent placement.



Id.



Id.

Visualization / Edit Tools	• Lumen Wall • Vessel Wall • Segment • Stenosis • Centerline • Plaque • Chronic Total Occlusion (CTO) • Stent • Exclude • Distance
2D Imaging	Yes
3D Imaging	Yes
Multiplanar Reformat (MPR)	Yes
Segmentation of region of interest	Manual and Semi-Automatic

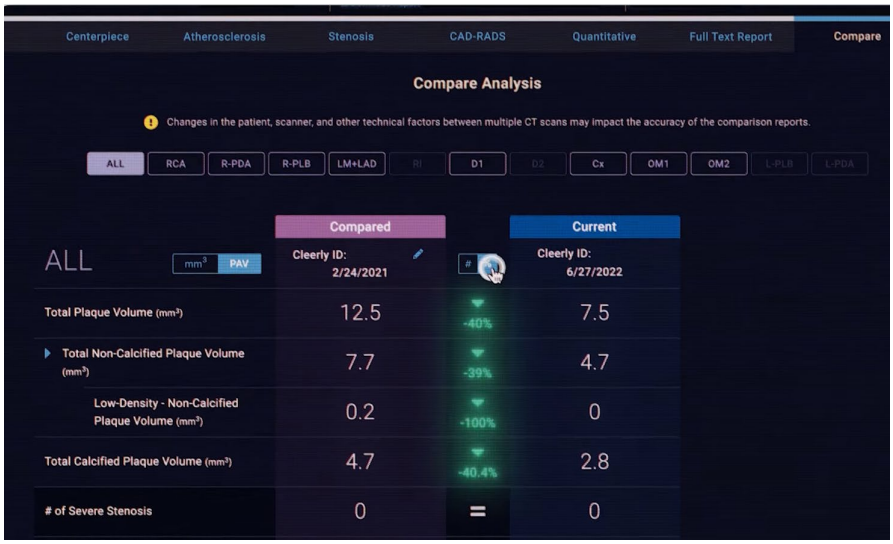
Quantification	
Hounsfield Unit (HU)	Yes
Distance Measurements	• Vessel • Lesion • Length
Volumetric Measurements	• Total Vessel • Total Lumen • Non-Calcified Plaque (NCP) • Low-Density Non-Calcified Plaque (LD-NCP) • Calcified Plaque (CP) • Total Plaque
Remodeling Index	Yes
Stenosis	• % Area Stenosis • % Diameter Stenosis

Id.

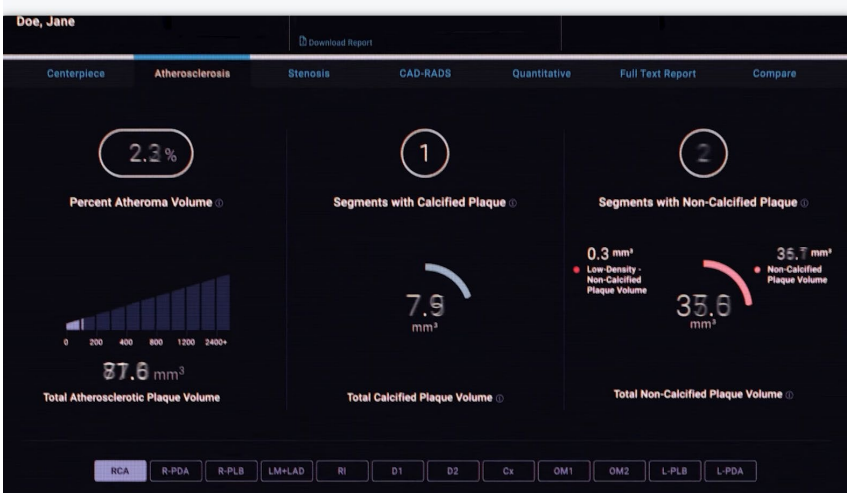
230. Upon information and belief, the Accused '399 Cleerly Products analyze additional characteristics, including ostial disease, tortuosity, thrombus, and diffuse disease, through discovery. *See* Ex. 41 (https://cleerlyhealth.com/what-is-cleerly) (provider reports with dominance, lesion-specific data, and CAD-RADS); Ex. 47 (FDA 510(k) Premarket Notification K202280 (Cleerly Labs v2.0), https://www.accessdata.fda.gov/cdrh_docs/pdf20/K202280.pdf) (CTO tools, stent indication, segment-level stenosis).

231. At least Claim 2 also requires automatically evaluating, using the at least one computer system, each of the determined multiple characteristics of the analyzed one or more geometric features of the one or more arteries, by automatically generating a numerical measurement of at least part of each characteristic. Upon information and belief, the '399 Cleerly Products uses deep learning for centerline and lumen/vessel segmentation and/or a random-forest model trained on a large database, including patients with invasive FFR, applying the learned

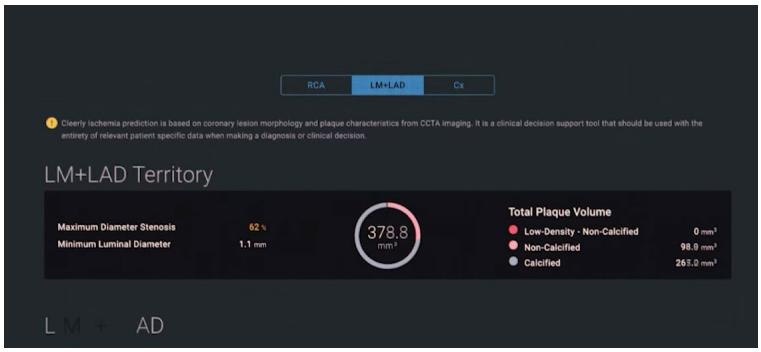
model to new cases to assist evaluation and ischemia prediction or plaque analysis both of which generate numerous numerical measurements for each characteristic. *See* Ex. 51 (CLARIFY, https://doi.org/10.1016/j.jcct.2021.05.004) (deep convolutional neural networks for centerline, lumen/vessel wall contouring, and plaque characterization); Ex. 53 (Bär et al., Prognostic value of a novel artificial intelligence-based coronary computed tomography angiography-derived ischemia algorithm, https://pmc.ncbi.nlm.nih.gov/articles/PMC11057943/) (random-forest machine-learned algorithm using 38 CCTA-derived quantitative variables from Cleerly Labs to predict abnormal invasive FFR).



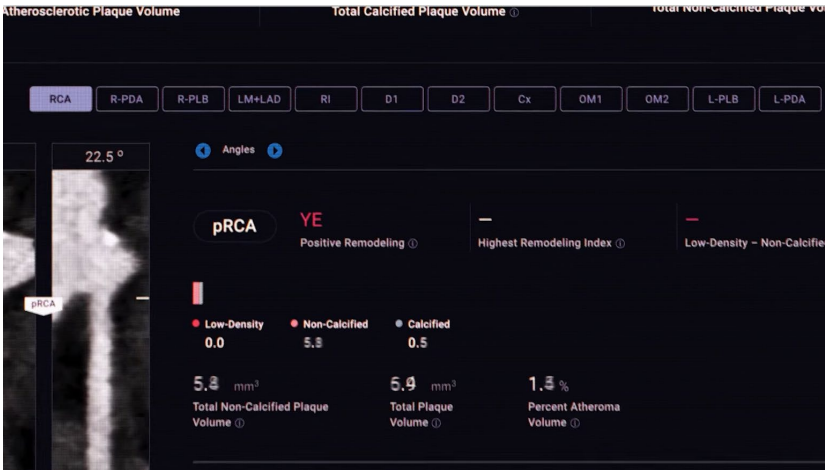
https://cleerlyhealth.com/ (Ex. 29)



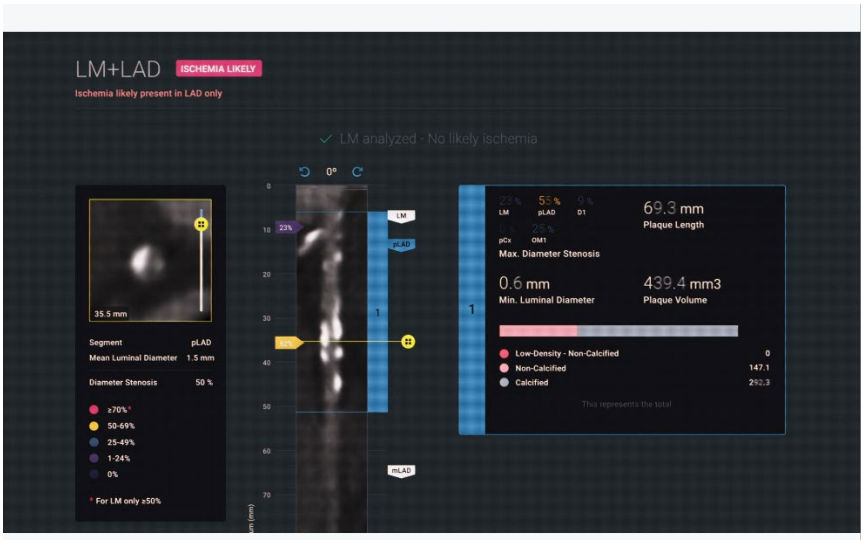
https://cleerlyhealth.com/ (Ex. 29)



Id.



Id.



Id.

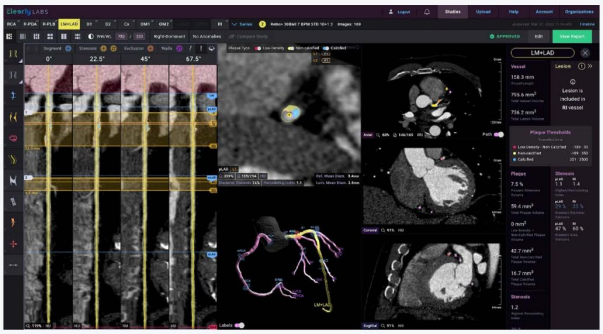
232. At least Claim 2 also requires automatically assign a point value to each of the multiple characteristics based on the evaluation and automatically execute an algorithm using the assigned point values to generate a cardiovascular score. Upon information and belief, the '399 Cleerly Products, execute an algorithm for one or more of Cleerly Plaque or Cleerly ISCHEMIA to assign a point value and to generate numerous cardiovascular scores including, but not limited to, quantitative per-vessel and per-lesion measurements, the Coronary Report's ischemia-likely presentation, and the Cleerly ISCHEMIA Index as a machine-learning output with an FFR-equivalent decision threshold. *See* Ex. 48 (FDA 510(k) Premarket Notification K190868 (Cleerly Labs), https://www.accessdata.fda.gov/cdrh_docs/pdf19/K190868.pdf); Ex. 47 (FDA 510(k) Premarket Notification K202280 (Cleerly Labs v2.0), https://www.accessdata.fda.gov/cdrh_docs/pdf20/K202280.pdf); Ex. 55 (FDA 510(k) Premarket Notification K231335 (Cleerly ISCHEMIA), https://www.accessdata.fda.gov/cdrh_docs/pdf23/K231335.pdf).

Cleerly uses proprietary and FDA-cleared machine learning algorithms to non-invasively measure atherosclerosis (plaque), stenosis, and likelihood of ischemia using coronary computed tomography angiography (CCTA) studies.

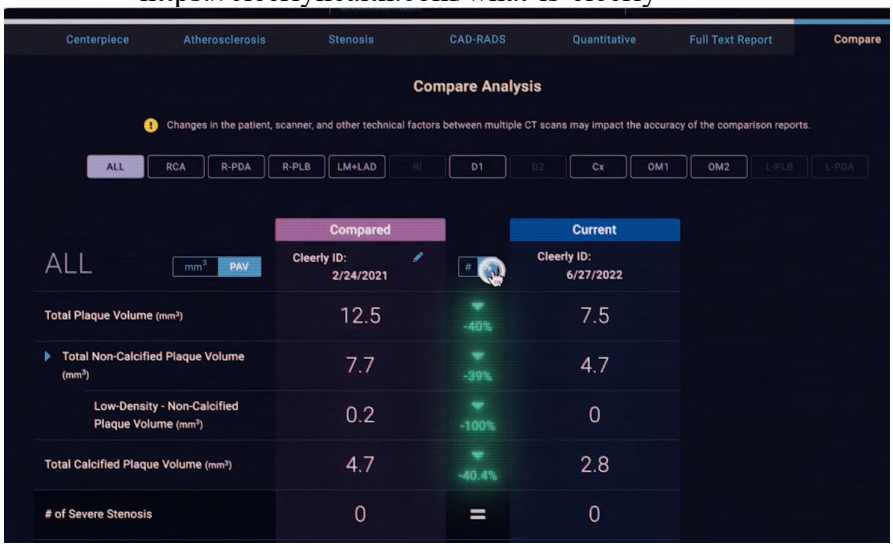
Our machine-learning AI generates a 3D model of the patient's coronary arteries, identifies their lumen and vessel walls, locates and measures stenoses, while quantifying and categorizing plaque.[1] Cleerly ISCHEMIA's algorithm uses measurements based on invasive FFR data to determine the likelihood of vessel-level ischemia.[2]

These sets of quantitative measurements are presented in a comprehensive report to support providers in efficient diagnosis and personalized patient treatment. Physicians can also review results in depth via our interactive web platform.

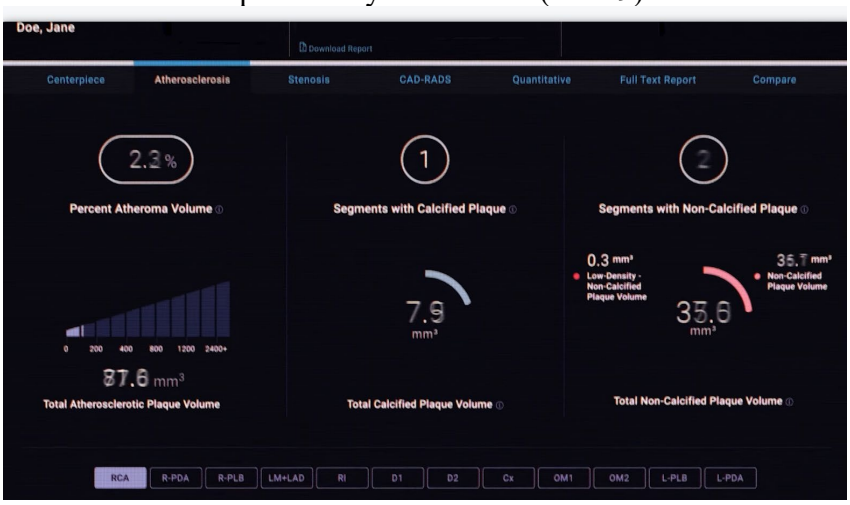
Cleerly's analyses are grounded in science, based on over 10 million images from over 40,000 patients gathered over a 15-year-period in landmark, multi-center clinical trials.[3] In a number of clinical studies, Cleerly has shown to be comparable to invasive gold standards, including IVUS[4], NIRS[5], FFR[6], OCT[7] and QCA.[8]



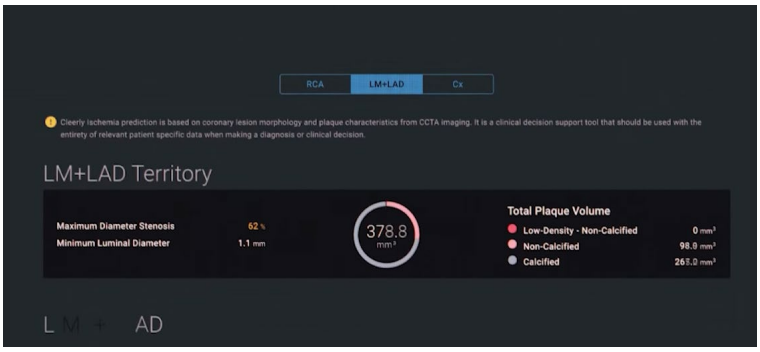
https://cleerlyhealth.com/what-is-cleerly



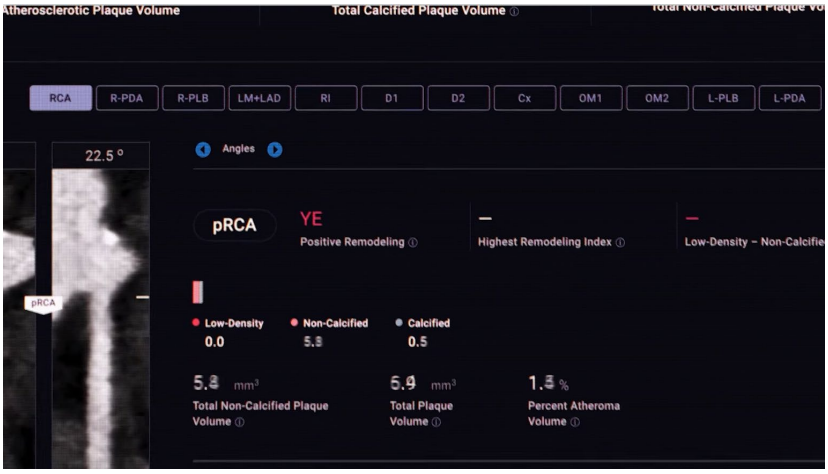
https://cleerlyhealth.com/ (Ex. 29)



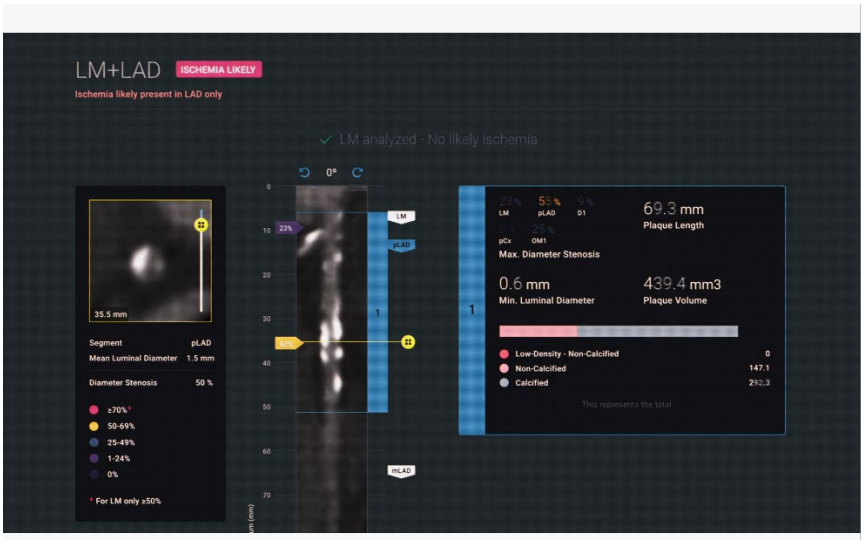
https://cleerlyhealth.com/ (Ex. 29)


RCA
LM+LAD
Cx
LM+LAD Territory
Maximum Diameter Stenosis
62 %
Minimum Luminal Diameter
1.1 mm
378.8
mm³
Total Plaque Volume
Low-Density - Non-Calcified
Non-Calcified
Calcified

Id.

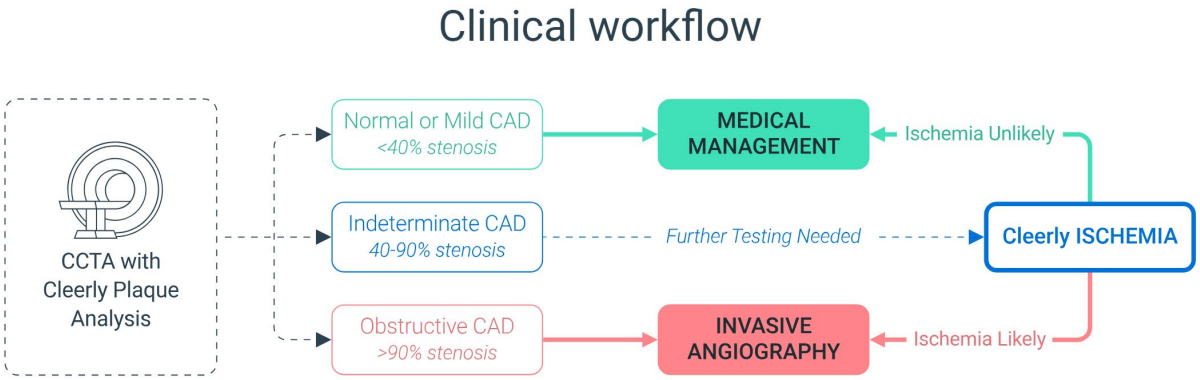

Total Calcified Plaque Volume
RCA
R-PDA
R-PLB
LM+LAD
RI
D1
D2
Cx
OM1
OM2
L-PLB
L-PDA
22.5 °
Angles
pRCA
YE
Positive Remodeling
Highest Remodeling Index
Low-Density - Non-Calcifie
Low-Density
0.0
Non-Calcified
Calcified
0.5
mm³
Total Non-Calcified Plaque Volume
Total Plaque Volume
%
Percent Atheroma Volume

Id.


LM+LAD
ISCHEMIA LIKELY
Ischemia likely present in LAD only
LM analyzed - No likely ischemia
0°
35.5 mm
Segment
pLAD
Mean Luminal Diameter
1.5 mm
Diameter Stenosis
50 %
≥70%*
50-69%
25-49%
1-24%
0%
* For LM only ≥50%
LM
pLAD
mLAD
69.3 mm
Plaque Length
Max. Diameter Stenosis
0.6 mm
Min. Luminal Diameter
439.4 mm3
Plaque Volume
Low-Density - Non-Calcified
Non-Calcified
Calcified

Id.

233. At least Claim 2 also requires receiving the patient-specific data comprises receiving data generated from a noninvasive imaging modality. Upon information and belief, the '399 Cleerly Products, receive data generated from a noninvasive imaging modality to perform one or more of Cleerly Plaque or Cleerly ISCHEMIA analysis.



https://cleerlyhealth.com/ischemia-reinvented (Ex. 26)

Cleerly uses proprietary and FDA-cleared machine learning algorithms to non-invasively measure atherosclerosis (plaque), stenosis, and likelihood of ischemia using coronary computed tomography angiography (CCTA) studies.

Our machine-learning AI generates a 3D model of the patient's coronary arteries, identifies their lumen and vessel walls, locates and measures stenoses, while quantifying and categorizing plaque.[1] Cleerly ISCHEMIA's algorithm uses measurements based on invasive FFR data to determine the likelihood of vessel-level ischemia.[2]

https://cleerlyhealth.com/what-is-cleerly (Ex. 41)

234. Non-limiting exemplary evidence of infringement appears in Cleerly's user and technical guides for Cleerly Labs and Cleerly ISCHEMIA, including, but not limited to, statements confirming CCTA-based image ingestion, automated centerline and lumen/vessel segmentation, plaque characterization and thresholding by Hounsfield Units, chronic total occlusion and stent indications, dominance selection and display, quantitative per-vessel and per-lesion measurements, the Coronary Report's ischemia-likely presentation, and the Cleerly ISCHEMIA

Index as a machine-learning output with an FFR-equivalent decision threshold. *See* Ex. 48 (FDA 510(k) Premarket Notification K190868 (Cleerly Labs), https://www.accessdata.fda.gov/cdrh_docs/pdf19/K190868.pdf); Ex. 47 (FDA 510(k) Premarket Notification K202280 (Cleerly Labs v2.0), https://www.accessdata.fda.gov/cdrh_docs/pdf20/K202280.pdf); Ex. 55 (FDA 510(k) Premarket Notification K231335 (Cleerly ISCHEMIA), https://www.accessdata.fda.gov/cdrh_docs/pdf23/K231335.pdf).

235. Additional evidence of the Accused '399 Cleerly Products infringing Claims 2-6, 8-14, and 17-18 is included in the documents below, including representations Cleerly made in its FDA filings and details Cleerly disclosed about techniques it implements in the Accused '399 Cleerly Products in articles and appendices attached to the articles.

236. For example, an FDA submission dated September 22, 2020 includes representations by Cleerly that provide evidence of the Accused '399 Cleerly Products infringing one or more claims of the '399 Patent, including receiving non-invasive patient data, creating models, analyzing models, and, among other things, generate a cardiovascular score:

Cleerly Labs is a web-based software application that is intended to be used by trained medical professionals as an interactive tool for viewing and analyzing cardiac computed tomography (CT) data for determining the presence and extent of coronary plaques (i.e., atherosclerosis) and stenosis in patients who underwent Coronary Computed Tomography Angiography (CCTA) for evaluation of CAD or suspected CAD. This software post processes CT images obtained using any Computed Tomography (CT) scanner. The software provides tools for the measurement and visualization of coronary arteries.

Cleerly 510(k) Summary, K202280, September 22, 2020 (Ex. 47)

4. Device Description

Cleerly Labs is a post-processing web-based software application that enables trained medical professionals to analyze 2D/3D coronary images acquired from Coronary Computed Tomography Angiography (CCTA) scans. The software is a post-processing tool that aids in determining treatment paths for patients suspected to have coronary artery disease (CAD).

Cleerly Labs utilizes machine learning and simple rule-based mathematical calculation components which are performed on the backend of the software. The software applies deep learning methodology to identify high quality images, segment and label coronary arteries, and segment lumen and vessel walls. 2D and 3D images are presented to the user for review and manual editing. This segmentation is designed to improve efficiency for the user, and help shorten tedious, time-consuming manual tasks.

Cleerly Labs provides a visualization of the Cleerly Labs analysis in the CORONARY Report. The CORONARY Report uses data previously acquired from the Cleerly Labs image analysis to generate a visually interactive and comprehensive report that details the atherosclerosis and stenosis findings of the patient. This report is not intended to be the final report (i.e., physician report) used in patient diagnosis and treatment. Cleerly Labs provides the ability to send the text report page of the CORONARY Report to the user's PACS system.

Id.

6. Software Functionality

In Cleerly Labs, users can edit the lumen and vessel walls of the suggested segmentation, and demarcate stenosis and stents, to more efficiently perform coronary analysis. Users are provided with navigation and editing/visualization tools to aid in image analysis. Plaque (i.e., atherosclerosis) and stenosis measurements are outputted based on the fully user-editable segmentation of the coronary artery. The user is also provided with the ability to indicate coronary anatomical findings.

Following the completion of study analysis, an interactive CORONARY Report is generated (the subject device of this submission). The CORONARY Report summarizes the analysis data from Cleerly Labs by reporting them as findings on atherosclerosis and stenosis, which may be used as supporting data in the evaluation of CAD. Components of the CORONARY Report include data visualization and reporting features. **Table 4** below compares the key features of the subject and predicate devices.

Id.

237. An additional FDA submission dated October 9, 2019 includes representations by Cleerly that also provide evidence of the Accused '399 Cleerly Products infringing one or more claims of the '399 Patent:

Device Description

Cleerly Labs is a post-processing web-based software application that enables trained medical professionals to analyze 2D/3D coronary images acquired from Computed Tomography (CT) angiographic scans. The software is a post-processing tool that aids in determining treatment paths for patients suspected to have coronary artery disease (CAD).

The output of the software includes visual images of coronary arteries, distance and volume measurements of the lumen wall, vessel wall, and plaque, remodeling index as well as stenosis diameter and area. These measurements are based on user segmentation.

Cleerly 510(k) Summary, K190868, October 9, 2019 (Ex. 48)

- A Usability test was conducted with U.S. board certified radiologists and technicians to ensure the clinical acceptability of the device.
- The machine learning algorithms were evaluated by comparing the output of the software to that of the ground truth using multiple ground truthers.

Id.

Visualization / Edit Tools	• Lumen Wall • Vessel Wall • Segment • Stenosis • Centerline • Plaque • Chronic Total Occlusion (CTO) • Stent • Exclude • Distance	***Quantification***	
2D Imaging	Yes	*Hounsfield Unit (HU)*	Yes
3D Imaging	Yes	*Distance Measurements*	• Vessel • Lesion • Length
Multiplanar Reformat (MPR)	Yes	*Volumetric Measurements*	• Total Vessel • Total Lumen • Non-Calcified Plaque (NCP) • Low-Density Non-Calcified Plaque (LD-NCP) • Calcified Plaque (CP) • Total Plaque
Segmentation of region of interest	Manual and Semi-Automatic	*Remodeling Index*	Yes
		Stenosis	• % Area Stenosis • % Diameter Stenosis

Id.

Device Name

Cleerly ISCHEMIA

Indications for Use *(Describe)*

Cleerly ISCHEMIA analysis software is an automated machine learning-based decision support tool, indicated as a diagnostic aid for patients undergoing CT analysis using Cleerly Labs software. When utilized by an interpreting healthcare provider, this software tool provides information that may be useful in detecting likely ischemia associated with coronary artery disease. Patient management decisions should not be made solely on the results of the Cleerly ISCHEMIA analysis.

Ex. 55 (FDA 510(k) Summary for Cleerly ISCHEMIA (K231335), https://www.accessdata.fda.gov/cdrh_docs/pdf23/K231335.pdf).

4. Device Description

Cleerly ISCHEMIA is an add-on software module to Cleerly Labs (K202280, K190868) that determines the likely presence or absence of coronal vessel ischemia based on quantitative measures of atherosclerosis, stenosis, and significant vascular morphology from typically-acquired Coronary Computed Tomography Angiography images (CCTA). Cleerly ISCHEMIA, in conjunction with Cleerly Labs, outputs a Cleerly ISCHEMIA Index (CII), a binary indication of negative CII (likely absence of ischemia) or positive CII (likely presence of ischemia) with its threshold equivalent to invasive FFR >0.80 vs. ≤0.80, respectively, as identified in professional societal practice guidelines.

Id.

The Cleerly ISCHEMIA data workflow begins after the Cleerly Labs outputs are approved for a study. A pre-processing module evaluates the eligibility of a study or vessels within the study for the Cleerly ISCHEMIA algorithm. The presence of certain identified anomalies can make an entire study ineligible, whereas the presence of a stent or exclusion in a vessel can make just that vessel ineligible. For all eligible vessels within a study, relevant Cleerly Labs outputs are aggregated from the default segment level to vessel level as the inputs to the Cleerly ISCHEMIA algorithm to determine the likely presence of ischemia. The results will then be evaluated by a post-processing module, which ensures that vessels subtended to a likely ischemic vessel are also marked as likely ischemic. The Cleerly ISCHEMIA algorithm outputs a Cleerly ISCHEMIA Index (CII), a binary indication of likely ischemia presence vs absence for a given vessel, which is equivalent to invasive FFR ≤0.80 vs. >0.80, respectively. Invasive FFR is a widely accepted gold-standard for determining vessel-specific ischemia. The Cleerly ISCHEMIA algorithm is "locked," meaning it is not a continuous learning algorithm.

Cleerly ISCHEMIA Index (likely ischemia / not likely ischemia) is displayed visually by Cleerly Labs to show the likely presence or absence of ischemia within epicardial coronary artery vessels. Vessels with Cleerly ISCHEMIA Index indicating likely ischemia presence (positive CII) are illuminated red, while vessels with Cleerly ISCHEMIA Index indicating likely ischemia absence (negative CII) are not illuminated. Cleerly ISCHEMIA analysis is intended to non-invasively support the functional evaluation of clinically stable symptomatic patients with coronary artery disease (CAD).

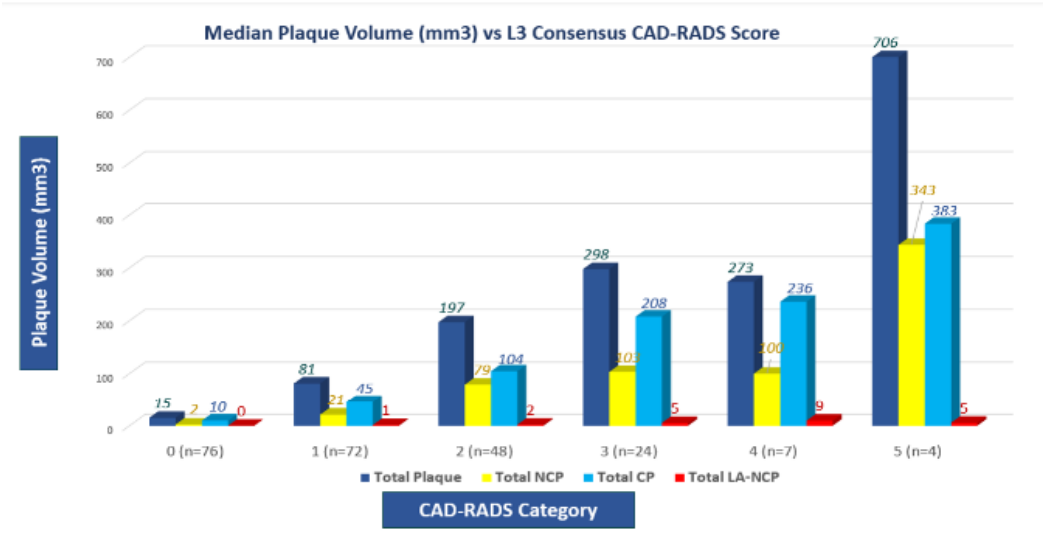
Id.

Supplement Figure 2: Contingency Tables of Level 3 Reader vs AI CAD-RADS Scores by CAD-RADS 0-3 and 4-5. These categories were chosen to represent a medical therapy (<70% stenosis) vs interventional (>70%) treatment threshold. On a per-vessel and per-patient basis, L3 and AI had 99.9% and 99.6% category agreement for these thresholds with weighted kappa values of 0.96 and 0.95 respectively.

Choi AD, et al. CT Evaluation of Coronary Artery Disease by AI: Appendix A (Ex. 50)

Supplement Figure 3: Example case of discordance between AI and Level 3 Expert Consensus. The most common disagreement between expert consensus reads and AI reads was expert consensus CAD-RADS 0 and AI CAD-RADS 1. In this example of a 56-year-old male with dyspnea and a strong family history of CAD, the expert consensus read was a CAD-RADS 0 with no stenosis and no plaque (Panel A: Proximal and mid left anterior descending coronary artery curved multiplanar reformation [MPR]; Panel B: axial image of proximal and mid left anterior descending). The AI depicted 82 mm^3 of circumferential noncalcified plaque in the mid LAD with no coronary stenosis (Panel C: A straightened MPR depicting AI segmentation of the lumen boundary [purple line] and outer vessel wall [yellow line], Panel D: Same image as Panel C with a color overlay of noncalcified plaque (density >30 and < 350 HU), Panel E: A short axis MPR generated at the mid plaque level [red line] from image C again depicting lumen [purple] and vessel wall outer boundaries [yellow]; Panel F: Same as Panel E with color overlay of the noncalcified plaque [density >30 and < 350 HU]).

Id.



Supplemental Figure 4: Median AI quantified plaque volume vs Level 3 Consensus by CAD-RADS Categorization. Quantified plaque volume showed a broad range of values across CAD-RADS categories. NCP = Non-calcified plaque; CP = Calcified plaque; LA-NCP = Low attenuation non-calcified plaque

Id.

238. Further, upon information and belief, the functionality of the Accused '399 Cleerly Products is described in the paper titled "CT Evaluation by Artificial Intelligence for Atherosclerosis, Stenosis and Vascular Morphology (CLARIFY): A Multi-center, international study" (Ex. 51), which also provides additional evidence that the Accused '399 Cleerly Products infringe one or more claims of the '399 Patent:

Artificial Intelligence Segmentation and Plaque Quantification. CCTA studies were uploaded to and analyzed by FDA-cleared software Cleerly LABS (Cleerly, New York, New York).[17,18] The three sites contributing cases were not used for software development or validation. This study is an investigator initiated study and Cleerly had no role in the study design or performance. Cleerly performed AI-aided CCTA analyses for the study in a blinded manner, and provided statistical services as determined and requested by study investigators.

This is an AI-aided approach (**Central Illustration**) that performs automated analysis of CCTA using a series of validated convolutional neural network models (including VGG 19 network, 3D U-Net and VGG Network Variant) for image quality assessment, coronary segmentation and labeling, lumen wall evaluation and vessel contour determination and plaque characterization.[10,19] A full graphical representation of the algorithm with validation details is presented in Appendix B. First, the AI-aided approach leverages 2 deep convolutional neural networks to

Id.

> Readers determined presence of two high risk plaque features—low attenuation plaque <30 Hounsfield units (HU) and positive arterial remodeling with a remodeling index ≥1.10 by diameter—with this analysis compared with AI on per vessel and per patient basis. This binary outcome was compared by calculating the percent agreement and kappa statistic.

Id.

> *CAD-RADS Categorization.* Fig. 1 depicts consensus reads versus AI results. Overall, 182/232 (78.0%) had CAD-RADS categorical agreement, 228/232(98.3%) agreed within one category. The most frequent disagreement occurred with expert consensus CAD-RADS 0 and AI CAD-RADS 1 (n = 29 12.5% per patient, n = 161 17.4% per vessel). To further evaluate L3 consensus vs AI for a collated mild-moderate versus severe stenosis categories, at a threshold for potential interventional treatment (>70% stenosis), we evaluated CAD-RADS 0–3 and CAD-RADS 4–5 to assess accuracy and found only 1 case of discrepancy on either a per-

Id.

239. The foregoing features and capabilities of each of the Accused '399 Cleerly Products description and/or demonstration thereof, including in advertising, reflect Cleerly's direct infringement by satisfying every element of at least Claims 2-6, 8-14, and 17-18 of the '399 Patent under 35 U.S.C. § 271(a).

240. Upon information and belief, Cleerly has induced infringement, and continues to induce infringement, of one or more Claims 2-6, 8-14, and 17-18 of the '399 Patent by actively and knowingly inducing others, including health care providers and hospitals in the Eastern District of Texas and throughout the United States, to directly infringe one or more claims of the '399 Patent through the use of Cleerly's products and services. For example, Cleerly instructs hospital employees and doctors, and induces patients through its website, via generating tutorial videos for training purposes, training hospital employees, conducting webinars, conducting demos at events, and/or producing instructional videos to induce them to directly infringe one or more claims of the '399 Patent through the use of the Accused '399 Cleerly Products. *See* https://www.youtube.com/@cleerlyhealth/videos (Ex. 42); https://cleerlyhealth.com/clinical-

publications; https://cleerlyhealth.com/blog; https://cleerlyhealth.com/webinars; https://cleerlyhealth.com/events.

241. Upon information and belief, Cleerly has contributed to the infringement of one or more of Claims 2-6, 8-14, and 17-18 of the '399 Patent by providing products and services that constitute material parts of the claimed inventions, knowing the same to be especially made or adapted for use in an infringing manner. For example, the Accused '399 Cleerly Products include at least one component to generate images and implement CNN to be used in conjunction with the Cleerly Platform to perform CAD detection. This is a component of a patented machine, manufacture, or combination, or an apparatus for use in practicing a patented process. Furthermore, such component is a material part of the invention and upon information and belief is not a staple article or commodity of commerce suitable for substantial non-infringing use. Thus, Cleerly is liable for infringement of the '399 Patent pursuant to 35 U.S.C. § 271(c).

242. Upon information and belief, Cleerly has been on notice of the '399 Patent at least since its issuance, and Cleerly's infringement of the '399 Patent has been and continues to be willful. For example, Cleerly, through its founder, Dr. James K. Min, had actual knowledge of Heartflow's patent portfolio through Dr. Min's role as a Heartflow consultant from 2012 to 2017, his execution of an NDA and Consulting Agreement with Heartflow, and his role as lead investigator on Heartflow's DeFACTO study. Dr. Min incorporated Cleerly on July 19, 2016 while still subject to the Consulting Agreement and its confidentiality, non-compete, and invention assignment obligations. Cleerly further acquired actual knowledge of Heartflow's patents through its hiring of Brent Ness, Heartflow's former Chief Commercial Officer, who was bound by confidentiality obligations under the Ness Agreement and Separation Agreement. Cleerly has

knowledge about the ’399 Patent based on Cleerly citing the ’399 Patent repeatedly in its own patents as seen below:

Heartflow’s Patent	**Cleerly Patent Citing Heartflow’s Patent**
US9839399	US10813612B2 US11094060B1 US11210786B2 US11861833B2 US11922627B2 US12144669B2 US12380560B2 US12440180B2 US12555228B2

243. By the time of trial, Cleerly will thus have known and intended (since receiving such notice), that its continued actions would actively induce and contribute to actual infringement of one or more Claims 2-6, 8-14, and 17-18 of the ’399 Patent.

244. Despite this actual knowledge of Heartflow’s patents, Cleerly deliberately chose to develop and commercialize infringing products rather than seek a license of those patents.

245. Cleerly undertook and continues its infringing actions despite an objectively high likelihood that such activities infringed the ’399 Patent, which has been duly issued by the USPTO and is presumed valid. For example, Cleerly has been aware of an objectively high likelihood that its actions constituted, and continue to constitute, infringement of the ’399 Patent based on Dr. Min’s actual knowledge and Cleerly’s knowledge as shown on Cleerly’s own patents, and that the ’399 Patent is valid. On information and belief, Cleerly cannot reasonably, subjectively believe that its actions do not constitute infringement of the ’399 Patent, nor could it reasonably, subjectively believe that the patent is invalid. Despite that knowledge and subjective belief, and

the objectively high likelihood that its actions constitute infringement, Cleerly has continued its infringing activities. As such, Cleerly willfully infringes the ’399 Patent.

246. Heartflow has been damaged by Cleerly’s infringement of the ’399 Patent and is entitled to recover damages adequate to compensate for such infringement pursuant to 35 U.S.C. § 284.

COUNT 5 – CLEERLY’S INFRINGEMENT OF U.S. PATENT NO. 9,607,386

247. Heartflow incorporates all preceding paragraphs by reference.

248. U.S. Patent No. 9,607,386 (the “’386 Patent”) was duly issued on March 28, 2017, and is titled “Systems and methods for correction of artificial deformation in anatomic modeling.” A copy of the ’386 Patent is attached as Exhibit 11.

249. Heartflow is the owner by assignment of the ’386 Patent and possesses all rights under the ’386 Patent, including the exclusive right to recover for past and future infringement.

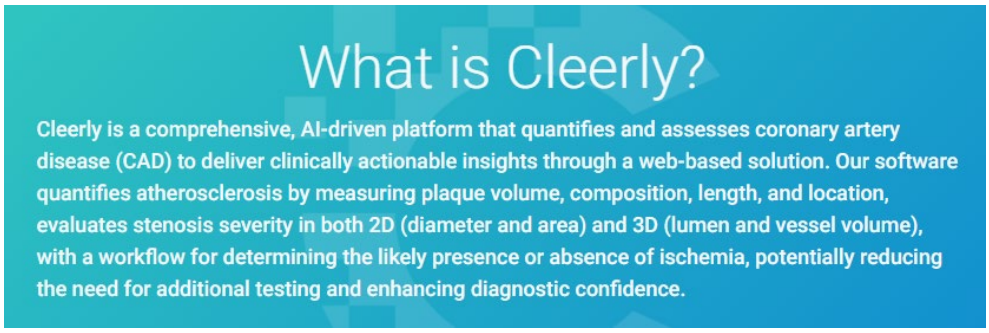
250. The ’386 Patent is directed to novel and inventive technology for correcting artificial deformations in anatomic models derived from medical images so that downstream measurements and visuals reflect true anatomy rather than artifacts. The ’386 Patent explains that artifacts from imaging or surrounding anatomy—including misregistration, motion artifacts, and myocardial bridging—may cause a vessel model to exhibit significant deformations where no actual pathology exists, compromising medical assessments such as measuring minimal lumen diameter, performing blood flow simulations, and calculating geometric characteristics of a blood vessel. ’386 Patent at 2:15–55, 4:5–35.

251. The ’386 Patent addresses these problems by providing methods that receive an anatomic model, identify portions affected by artificial deformation, estimate a local area for a non-deformed anatomy using proximal and/or distal vessel radii, and modify the model

accordingly, with the modified model then available for simulations and further medical assessments. *Id.* at 4:40–5:35, 6:35–7:15. Claims 2-4, 7, and 8 address artifact sources such as motion or misregistration, blood-vessel embodiments, simulations on the corrected model, and obtaining artifact-indicating information via user input or computations between images and segmentation algorithms. *See* '386 Patent at Claims 2–4, 7, 8, 10-12, 15, 16, and 18-20, Abstract; Figs. 2–4.

252. Evidence that the '386 Patent is valid and is directed to novel and inventive technology is discussed above in at least paragraphs 17-41 and 96-103 and incorporated by reference. Further, the '386 Patent has been recognized as a foundational patent as shown by the fact that it has been cited in over 30 additional patents, including patents filed by Stenomics, Inc., Elucid Bioimaging Inc., and Emory University whereas Cleerly has cited the family members of the '386 Patent.

253. Upon information and belief, Cleerly has directly infringed, and continues to directly infringe, one or more claims of the '386 Patent in this District and elsewhere in Texas, including at least Claims 2–4, 7, 8, 10-12, 15, 16, and 18-20 literally and/or under the doctrine of equivalents, making, using, selling, offering to sell, and/or importing into the United States products and services that practice the inventions claimed therein, including, but not limited to, Cleerly Plaque Analysis and Cleerly ISCHEMIA (collectively, "the Accused '386 Cleerly Products"). For example, Cleerly provides a "comprehensive, AI-driven platform that quantifies and assesses coronary artery disease (CAD)" that "quantifies atherosclerosis by measuring plaque volume, composition, length, and location, evaluates stenosis severity in both 2D (diameter and area) and 3D (lumen and vessel volume), with a workflow for determining the likely presence or absence of ischemia." https://cleerlyhealth.com/ (Ex. 29).

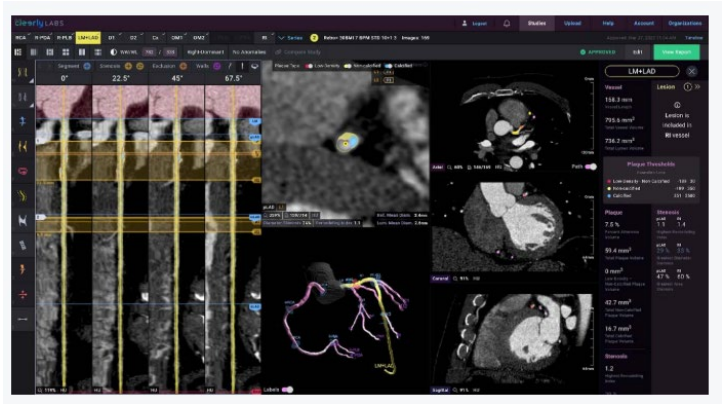


https://cleerlyhealth.com/ (Ex. 29)

Cleerly uses proprietary and FDA-cleared machine learning algorithms to non-invasively measure atherosclerosis (plaque), stenosis, and likelihood of ischemia using coronary computed tomography angiography (CCTA) studies.

Our machine-learning AI generates a 3D model of the patient's coronary arteries, identifies their lumen and vessel walls, locates and measures stenoses, while quantifying and categorizing plaque.[1] Cleerly ISCHEMIA's algorithm uses measurements based on invasive FFR data to determine the likelihood of vessel-level ischemia.[2]

https://cleerlyhealth.com/what-is-cleerly (Ex. 41)

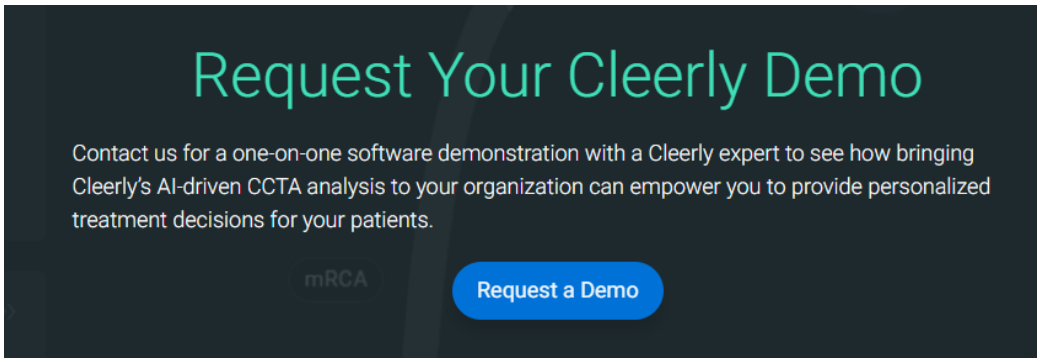


https://cleerlyhealth.com/what-is-cleerly (Ex. 41)

https://cleerlyhealth.com/what-is-cleerly (Ex. 41)

254. Heartflow reserves the right to discover and pursue any additional infringing products and services that incorporate infringing functionalities. For the avoidance of doubt, the Accused '386 Cleerly Products are identified to describe Cleerly's infringement and in no way limit the discovery and infringement allegations against Cleerly concerning other products that incorporate the same or reasonably similar functionalities.

255. Upon information and belief, Cleerly directly infringes one or more of Claims 2–4, 7, 8, 10-12, 15, 16, and 18-20 of the '386 Patent by performing one or more method claims in the United States when, for example, performing testing including "usability tests" as confirmed in FDA submissions, generating tutorial videos for training purposes, training hospital employees, conducting webinars, conducting demos at events, and/or producing instructional videos showing how the Accused '386 Cleerly Products operate. https://www.youtube.com/@cleerlyhealth/videos (Ex. 42); https://cleerlyhealth.com/clinical-publications; https://cleerlyhealth.com/blog; https://cleerlyhealth.com/webinars; https://cleerlyhealth.com/events.



256. Each of the Accused '386 Cleerly Products, either alone or in combination with each other, perform a computer-implemented method or implement a system and/or computer-readable medium of correcting anatomical modeling.

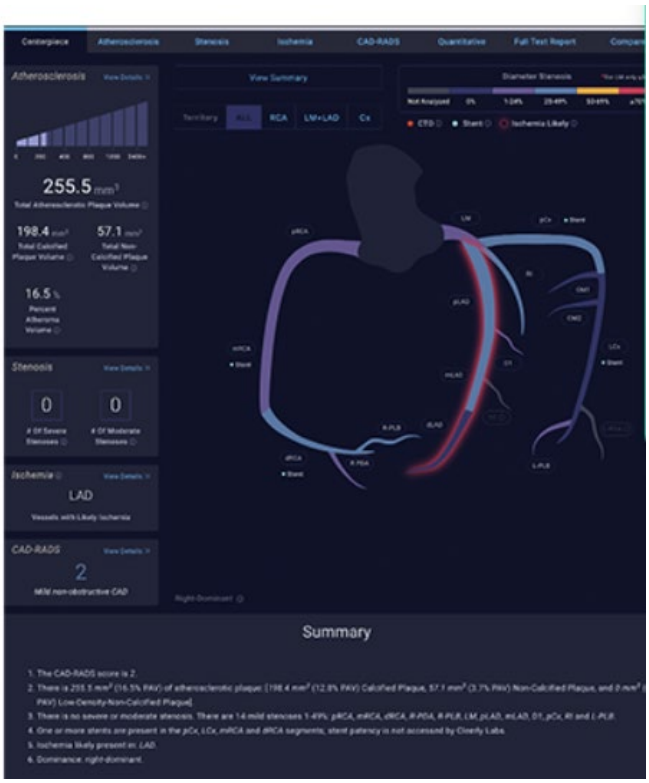
257. At least Claim 2—which depends from Claim 1 and includes the limitations of Claim 1—requires obtaining an anatomic model. Upon information and belief, Cleerly's "machine-learning AI generates a 3D model of the patient's coronary arteries, identifies their lumen and vessel walls, locates and measures stenoses, while quantifying and categorizing plaque." Ex. 41 (What is Cleerly, https://cleerlyhealth.com/what-is-cleerly). More specifically, Cleerly's AI-QCT platform "creates contouring for the centreline, lumen and outer vessel wall for all available phases, then selects the two best series for further analysis." Ex. 66 (Nurmohamed et al., Diagnostic accuracy in coronary CT angiography analysis, https://pmc.ncbi.nlm.nih.gov/articles/PMC11784206/). This 3D model with centerline, lumen, and vessel wall contouring constitutes an anatomic model as recited in Claim 1. Ex. 67 (Khan et al., Assessment of atherosclerotic plaque burden: comparison of AI-QCT versus SIS, CAC, visual and CAD-RADS stenosis categories, https://pmc.ncbi.nlm.nih.gov/articles/PMC11213790/).

4. Device Description

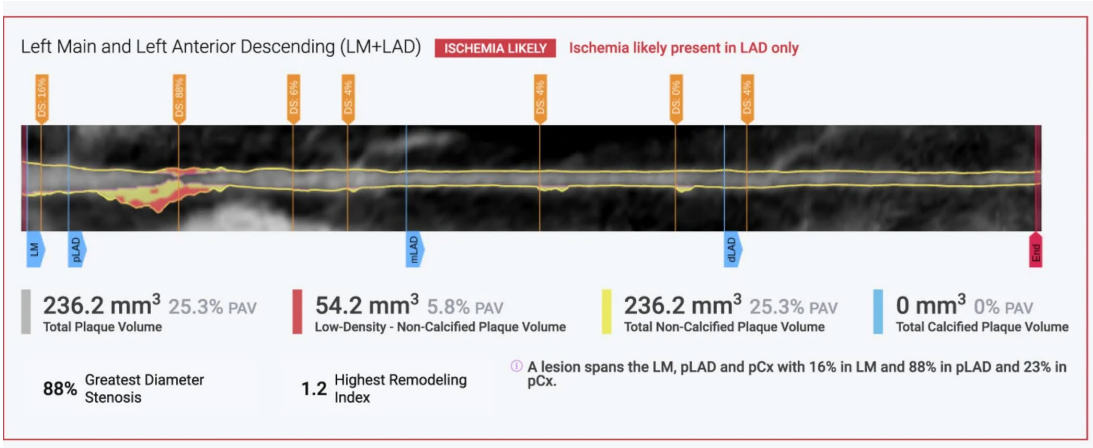
Cleerly Labs is a post-processing web-based software application that enables trained medical professionals to analyze 2D/3D coronary images acquired from Coronary Computed Tomography Angiography (CCTA) scans. The software is a post-processing tool that aids in determining treatment paths for patients suspected to have coronary artery disease (CAD).

Cleerly Labs utilizes machine learning and simple rule-based mathematical calculation components which are performed on the backend of the software. The software applies deep learning methodology to identify high quality images, segment and label coronary arteries, and segment lumen and vessel walls. 2D and 3D images are presented to the user for review and manual editing. This segmentation is designed to improve efficiency for the user, and help shorten tedious, time-consuming manual tasks.

Cleerly 510(k) Summary, K202280, September 22, 2020 (Ex. 47)



https://cleerlyhealth.com/what-is-cleerly (Ex. 41)



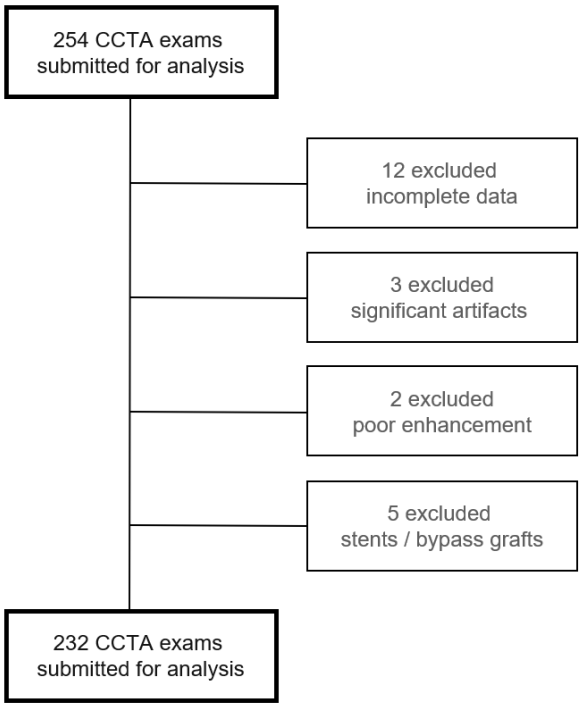
https://cleerlyhealth.com/patient-education (Ex. 35)

258. At least Claim 2 also requires obtaining information indicating a presence of an artificial deformation of the anatomic model. The ’386 Patent explains that artificial deformations may be caused by image artifacts (misregistration, streaking, stents, pacemaker leads, windmill artifacts), loss of contrast, or artificial constriction from surrounding tissue such as myocardial bridging. Upon information and belief, Cleerly’s platform identifies and accounts for artificial deformations in the anatomic model. In the CLARIFY and related studies, Cleerly excluded “exams with incomplete data, significant artifacts, poor enhancement, stents or bypass grafts,” meaning the software identifies the presence of such artifact-producing features. Ex. 67 (Khan et al., https://pmc.ncbi.nlm.nih.gov/articles/PMC11213790/).

259. In a case study using Cleerly’s platform in patients with end-stage renal disease and complex CAD, a stent present in the proximal right coronary artery “was excluded from QCT analysis (purple overlay with 'N' markers),” demonstrating that Cleerly identifies the presence of artificial deformations (here, a stent) and marks them in the anatomic model. Ex. 68 (Cho et al., Quantitative plaque analysis with A.I.-augmented CCTA in end-stage renal disease and complex CAD, https://pubmed.ncbi.nlm.nih.gov/35835019/). Upon information and belief, the Accused ’386 Cleerly Products include “software [that] uses an array of validated convolutional neural networks to assess image quality,” which would include identifying the presence of deformities by, for example, applying deep learning methodologies. Ex. 69 (Nurmohamed et al., https://pmc.ncbi.nlm.nih.gov/articles/PMC11784206/).

260. Upon information and belief, the Accused ’386 Cleerly Products include a function to exclude regions with artifacts directly and use a series of validated convolutional neural network models (including VGG19 network, 3D U-Net, and VGG Network Variant that produce an

identical result each iteration) for image quality assessment" and that they can select when one data is of better image quality than another. https://doi.org/10.1007/s10554-024-03087-x



Choi AD, et al. CT Evaluation of Coronary Artery Disease by AI: Appendix A (Ex. 50)

Cleerly Labs utilizes machine learning and simple rule-based mathematical calculation components which are performed on the backend of the software. The software applies deep learning methodology to identify high quality images, segment and label coronary arteries, and segment lumen and vessel walls. 2D and 3D images are presented to the user for review and manual editing. This segmentation is designed to improve efficiency for the user, and help shorten tedious, time-consuming manual tasks.

Cleerly 510(k) Summary, K202280, September 22, 2020 (Ex. 47)

261. At least Claim 2 also requires identifying a portion of the anatomic model associated with the artificial deformation. Upon information and belief, the Accused '386 Cleerly Products identifies specific portions of the coronary vessel model associated with artificial deformations. In the Cho et al. case study, the stented segment was precisely identified and marked within the anatomic model with specific "N" markers, delineating the portion of the vessel affected

by the stent artifact. This exclusion "represented 2.82% of the coronary vessels measuring 2 mm or greater." Ex. 68 (Cho et al., https://pubmed.ncbi.nlm.nih.gov/35835019/). Furthermore, academic literature has acknowledged that challenges remain in AI-CCTA regarding "coronary anomalies, myocardial bridging, and imaging artefacts," indicating that the identification of such affected portions is an integral part of the CCTA analysis workflow. Ex. 69 (van Assen et al., Artificial intelligence for advanced analysis of coronary plaque, https://pmc.ncbi.nlm.nih.gov/articles/PMC10132604/).

262. At least Claim 2 also requires estimating a vessel radius based on the anatomic model, the vessel radius being a vessel radius proximal to the artificial deformation, a vessel radius distal to the artificial deformation, or a constant radius of a vessel of the anatomic model. Upon information and belief, Cleerly's AI-QCT algorithm calculates stenosis "using an interpolated reference diameter at the site of stenosis." Specifically, "per cent diameter stenosis within a segment was represented by 1 minus the ratio of the lumen diameter at the site of maximal obstruction divided by the estimated normal lumen diameter at this site by interpolation of the normal proximal and normal distal reference vessel × 100." Ex. 66 (Nurmohamed et al., https://pmc.ncbi.nlm.nih.gov/articles/PMC11784206/). This interpolation of the "normal proximal and normal distal reference vessel" constitutes an estimation of vessel radius (or diameter) based on measurements proximal and distal to a given location, as recited in Claim 1. Separately, the CREDENCE trial substudy confirmed that with Cleerly, "stenosis was calculated using a healthy reference area to provide a maximal coronary stenosis output." Ex. 43 (Griffin et al., AI Evaluation of Stenosis on Coronary CTA, Comparison With Quantitative Coronary Angiography and Fractional Flow Reserve: A CREDENCE Trial Substudy, https://www.sciencedirect.com/science/article/pii/S1936878X22000018).

263. At least Claim 2 also requires estimating, based on the estimated vessel radius, a non-deformed local area corresponding to the portion of the anatomic model. Upon information and belief, Cleerly's interpolation of the "normal proximal and normal distal reference vessel" to determine an "estimated normal lumen diameter" at a site of interest necessarily constitutes estimating a non-deformed local area for the vessel. Ex. 66 (Nurmohamed et al., https://pmc.ncbi.nlm.nih.gov/articles/PMC11784206/). The "healthy reference area" used by Cleerly to calculate stenosis represents Cleerly's estimate of what the vessel's local area would be in a non-deformed (i.e., non-stenosed or non-artifactually narrowed) state. Ex. 43 (Griffin et al., https://www.sciencedirect.com/science/article/pii/S1936878X22000018). This approach is functionally consistent with the '386 Patent's described technique of estimating a local area for a non-deformed anatomy by measuring the radius proximal and/or distal to the deformation and computing an estimated non-deformed area.

264. At least Claim 2 also requires modifying the portion of the anatomic model associated with the artificial deformation, based on the estimated non-deformed local area. Upon information and belief, the Accused '386 Cleerly Products modify its anatomic model in portions affected by artificial deformations. In the stented segment example from Cho et al., the stented portion of the vessel was excluded from quantitative plaque analysis and replaced with a distinct overlay (purple with "N" markers), while analysis continued on the rest of the coronary vessel model. Ex. 68 (Cho et al., https://pubmed.ncbi.nlm.nih.gov/35835019/). This constitutes a modification of the model's treatment of the artifactually deformed segment. Additionally, the use of the interpolated "estimated normal lumen diameter" from proximal and distal reference vessels, rather than the actual measured lumen at a site of maximal obstruction, represents a modification

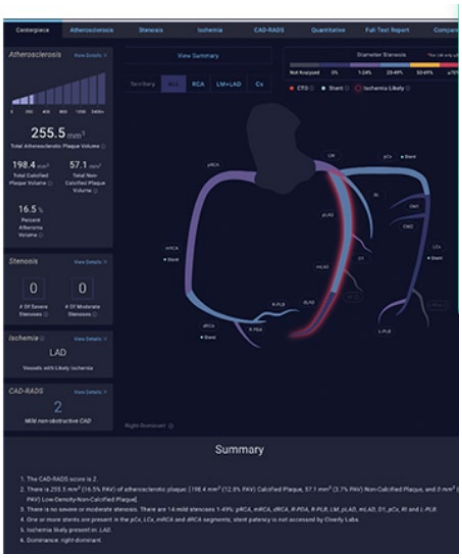
of the model to substitute an estimated non-deformed geometry. Ex. 66 (Nurmohamed et al., https://pmc.ncbi.nlm.nih.gov/articles/PMC11784206/).

Appendix B: Artificial Intelligence/Machine Learning Steps to CCTA Image Evaluation: The following figures present in graphical detail the stepwise use of artificial intelligence algorithms used for CCTA analysis.

This is an AI-aided approach (Cleerly Inc, New York, NY) that performs an automated analysis of CCTA using a series of validated convolutional neural network models (including VGG 19 network, 3D U-Net and VGG Network Variant) for image quality assessment, coronary segmentation and labeling, lumen wall evaluation and vessel contour determination and plaque characterization(19). No manual interaction is required from the reader. First, the AI-aided approach leverages 2 deep convolutional neural networks (VGG-19 Network and 3D U-Net) to produce a centerline along the length of the vessel, and then for lumen and outer vessel wall contouring. This approach is applied to multiple phases/series of the CCTA examination, if present, and enables phase-specific evaluation at the coronary segment vessel. The algorithm reviewed all series and determined the top 2 optimal series for further analysis including vessel and lumen segmentation, plaque, and stenosis quantification. The algorithm rank-orders all available phases for the segmentation of the arteries. It then uses the top two phases interactively on a per vessel basis, e.g., the right coronary artery (RCA) will be reconstructed from the phase which yields the highest RCA image quality, while the posterior descending artery (PDA) may come from the second phase if the PDA has a higher image quality on that phase. Once coronary artery segmentation is performed, an automated labeling is done to

Choi AD, et al. CT Evaluation of Coronary Artery Disease by AI: Appendix B (Ex. 49)

265. Further, the visual representation shown of the 3D scans with uniform lines provide evidence of modification to account for deformations.



https://cleerlyhealth.com/what-is-cleerly (Ex. 41)

266. At least Claim 2 also requires that the artificial deformation be based on a misregistration, a motion artifact, or myocardial bridging. Upon information and belief, the Accused '386 Cleerly Products modify its anatomic model in portions affected by artificial deformations such as one or more of misregistration, a motion artifact, or myocardial bridging. For example, challenges remain in AI-CCTA regarding "coronary anomalies, myocardial bridging, and imaging artefacts," indicating that the identification of such affected portions is an integral part of the CCTA analysis workflow. Ex. 69 (van Assen et al., Artificial intelligence for advanced analysis of coronary plaque, https://pmc.ncbi.nlm.nih.gov/articles/PMC10132604/). Further, the visual representation shown of the 3D scans with uniform lines provide evidence of modification to account for misregistration, a motion artifact, or myocardial bridging.

267. Additional evidence of the Accused '386 Cleerly Products infringing Claims 2–4, 7, 8, 10-12, 15, 16, and 18-20 is included in the documents below, including representations Cleerly made in its FDA filings and details Cleerly disclosed about techniques it implements in generating 2D and 3D models where artificial deformations are removed and smooth lines are shown by the Accused '386 Cleerly Products.

268. For example, an FDA submission dated September 22, 2020 includes representations by Cleerly that provide evidence of the Accused '386 Cleerly Products infringing one or more claims of the '386 Patent, including implementing "deep learning" and/or machine learning along with receiving images of anatomic structure, generating high quality 3D images by performing deep learning and performing image analysis on the corrected images:

Cleerly Labs is a web-based software application that is intended to be used by trained medical professionals as an interactive tool for viewing and analyzing cardiac computed tomography (CT) data for determining the presence and extent of coronary plaques (i.e., atherosclerosis) and stenosis in patients who underwent Coronary Computed Tomography Angiography (CCTA) for evaluation of CAD or suspected CAD. This software post processes CT images obtained using any Computed Tomography (CT) scanner. The software provides tools for the measurement and visualization of coronary arteries.

Cleerly 510(k) Summary, K202280, September 22, 2020 (Ex. 47)

4. Device Description

Cleerly Labs is a post-processing web-based software application that enables trained medical professionals to analyze 2D/3D coronary images acquired from Coronary Computed Tomography Angiography (CCTA) scans. The software is a post-processing tool that aids in determining treatment paths for patients suspected to have coronary artery disease (CAD).

Cleerly Labs utilizes machine learning and simple rule-based mathematical calculation components which are performed on the backend of the software. The software applies deep learning methodology to identify high quality images, segment and label coronary arteries, and segment lumen and vessel walls. 2D and 3D images are presented to the user for review and manual editing. This segmentation is designed to improve efficiency for the user, and help shorten tedious, time-consuming manual tasks.

Id.

6. Software Functionality

In Cleerly Labs, users can edit the lumen and vessel walls of the suggested segmentation, and demarcate stenosis and stents, to more efficiently perform coronary analysis. Users are provided with navigation and editing/visualization tools to aid in image analysis. Plaque (i.e., atherosclerosis) and stenosis measurements are outputted based on the fully user-editable segmentation of the coronary artery. The user is also provided with the ability to indicate coronary anatomical findings.

Id.

269. An additional FDA submission dated October 9, 2019 includes representations by Cleerly that also provide evidence of the Accused '386 Cleerly Products infringing one or more claims of the '386 Patent:

Device Description

Cleerly Labs is a post-processing web-based software application that enables trained medical professionals to analyze 2D/3D coronary images acquired from Computed Tomography (CT) angiographic scans. The software is a post-processing tool that aids in determining treatment paths for patients suspected to have coronary artery disease (CAD).

The output of the software includes visual images of coronary arteries, distance and volume measurements of the lumen wall, vessel wall, and plaque, remodeling index as well as stenosis diameter and area. These measurements are based on user segmentation.

Cleerly 510(k) Summary, K190868, October 9, 2019 (Ex. 48)

Visualization / Edit Tools	• Lumen Wall • Vessel Wall • Segment • Stenosis • Centerline • Plaque • Chronic Total Occlusion (CTO) • Stent • Exclude • Distance
2D Imaging	Yes
3D Imaging	Yes
Multiplanar Reformat (MPR)	Yes
Segmentation of region of interest	Manual and Semi-Automatic

Id.

270. The foregoing features and capabilities of each of the Accused '386 Cleerly Products description and/or demonstration thereof, including in advertising, reflect Cleerly's direct infringement by satisfying every element of at least Claims 2–4, 7, 8, 10-12, 15, 16, and 18-20 of the '386 Patent under 35 U.S.C. § 271(a).

271. Upon information and belief, Cleerly has induced infringement, and continues to induce infringement, of one or more Claims 2–4, 7, 8, 10-12, 15, 16, and 18-20 of the '386 Patent by actively and knowingly inducing others, including health care providers and hospitals in the Eastern District of Texas and throughout the United States, to directly infringe one or more claims of the '386 Patent through the use of Cleerly's products and services. For example, Cleerly instructs hospital employees and doctors, and induces patients through its website, via generating tutorial videos for training purposes, training hospital employees, conducting webinars, conducting demos at events, and/or producing instructional videos to induce them to directly

infringe one or more claims of the ’386 Patent through the use of the Accused ’386 Cleerly Products. *See* https://www.youtube.com/@cleerlyhealth/videos (Ex. 42); https://cleerlyhealth.com/clinical-publications; https://cleerlyhealth.com/blog; https://cleerlyhealth.com/webinars; https://cleerlyhealth.com/events.

272. Upon information and belief, Cleerly has contributed to the infringement of one or more Claims 2–4, 7, 8, 10-12, 15, 16, and 18-20 of the ’386 Patent by providing products and services that constitute material parts of the claimed inventions, knowing the same to be especially made or adapted for use in an infringing manner. For example, the Accused ’386 Cleerly Products include at least one component to generate images and 3D models without artificial deformities. This is a component of a patented machine, manufacture, or combination, or an apparatus for use in practicing a patented process. Furthermore, such component is a material part of the invention and upon information and belief is not a staple article or commodity of commerce suitable for substantial non-infringing use. Thus, Cleerly is liable for infringement of the ’386 Patent pursuant to 35 U.S.C. § 271(c).

273. Upon information and belief, Cleerly has been on notice of the ’386 Patent at least since its issuance, and Cleerly’s infringement of the ’386 Patent has been and continues to be willful. For example, Cleerly, through its founder, Dr. James K. Min, had actual knowledge of Heartflow’s patent portfolio through Dr. Min’s role as a Heartflow consultant from 2012 to 2017, his execution of an NDA and Consulting Agreement with Heartflow, and his role as lead investigator on Heartflow’s DeFACTO study. Dr. Min incorporated Cleerly on July 19, 2016 while still subject to the Consulting Agreement and its confidentiality, non-compete, and invention assignment obligations. Cleerly further acquired actual knowledge of Heartflow’s patents through its hiring of Brent Ness, Heartflow’s former Chief Commercial Officer, who was bound by

confidentiality obligations under the Ness Agreement and Separation Agreement. Cleerly has knowledge about the ’386 Patent based on Cleerly citing the family members of the ’386 Patent repeatedly in its own patents as seen below:

Heartflow’s Patent	**Cleerly Patents/Applications Citing Family Members of the ’386 Patent**
US 9,607,386	US 10,813,612 B2 US 11,969,280 B2 US 2022/0392065 A1 US 2025/0217981 A1 US 2025/0143657 A1 US 12,440,180 B2 US 12,406,365 B2

274. By the time of trial, Cleerly will thus have known and intended (since receiving such notice), that its continued actions would actively induce and contribute to actual infringement of one or more Claims 2–4, 7, 8, 10-12, 15, 16, and 18-20 of the ’386 Patent.

275. Despite this actual knowledge of Heartflow’s patents, Cleerly deliberately chose to develop and commercialize infringing products rather than seek a license of those patents.

276. Cleerly undertook and continues its infringing actions despite an objectively high likelihood that such activities infringed the ’386 Patent, which has been duly issued by the USPTO and is presumed valid. For example, Cleerly has been aware of an objectively high likelihood that its actions constituted, and continue to constitute, infringement of the ’386 Patent based on Dr. Min’s actual knowledge and Cleerly’s knowledge as shown on Cleerly’s own patents, and that the ’386 Patent is valid. On information and belief, Cleerly cannot reasonably, subjectively believe that its actions do not constitute infringement of the ’386 Patent, nor could it reasonably, subjectively believe that the patent is invalid. Despite that knowledge and subjective belief, and the objectively high likelihood that its actions constitute infringement, Cleerly has continued its infringing activities. As such, Cleerly willfully infringes the ’386 Patent.

277. Heartflow has been damaged by Cleerly's infringement of the '386 Patent and is entitled to recover damages adequate to compensate for such infringement pursuant to 35 U.S.C. § 284.

COUNT 6 – CLEERLY'S INFRINGEMENT OF U.S. PATENT NO. 11,013,425

278. Heartflow incorporates all preceding paragraphs by reference.

279. U.S. Patent No. 11,013,425 (the "'425 Patent") was duly issued on May 25, 2021, and is titled "Systems and methods for analyzing and processing digital images to estimate vessel characteristics." A copy of the '425 Patent is attached as Exhibit 12.

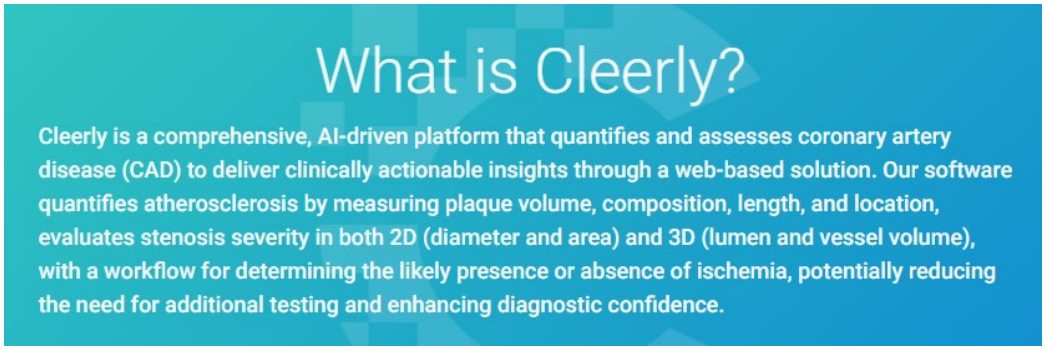
280. Heartflow is the owner by assignment of the '425 Patent and possesses all rights under the '425 Patent, including the exclusive right to recover for past and future infringement.

281. The '425 Patent is directed to computerized, patient-specific, noninvasive assessment of arterial physiology using image-derived arterial geometry and machine learning to predict physiologic values such as fractional flow reserve (FFR) and estimation of ischemia at locations of interest. The patent describes workflows that acquire patient-specific arterial geometry from medical images, create feature vectors that capture global and local anatomic and physiologic parameters, train machine-learning models on previously analyzed anatomy and physiology, and then compute per-location physiologic index values for new patients, with visualization of results. *See* '425 Patent at Abstract, Figs. 1–2.

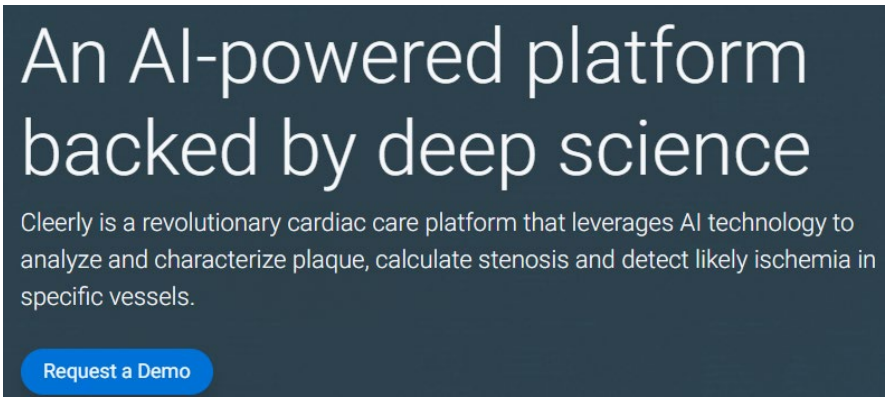
282. Evidence that the '425 Patent is valid and is directed to novel and inventive technology is discussed above in at least paragraphs 17-41 and 96-103 and incorporated by reference. Further, the '425 Patent has been recognized as a foundational patent as shown by the fact that it has been cited in over 140 additional patents and applications filed by a wide range of

entities operating in the fields of cardiovascular imaging, medical devices, and AI-driven diagnostics, including Cleerly, Elucid Bioimaging Inc., and Siemens Healthcare GmbH.

283. Upon information and belief, Cleerly has directly infringed, and continues to directly infringe, one or more claims of the '425 Patent in this District and elsewhere in Texas, including at least Claims 5-10, 15-17, and 20 literally and/or under the doctrine of equivalents, making, using, selling, offering to sell, and/or importing into the United States products and services that practice the inventions claimed therein, including, but not limited to, Cleerly Plaque Analysis and Cleerly ISCHEMIA (collectively, "the Accused '425 Cleerly Products"). For example, Cleerly provides a "comprehensive, AI-driven platform that quantifies and assesses coronary artery disease (CAD)" that "quantifies atherosclerosis by measuring plaque volume, composition, length, and location, evaluates stenosis severity in both 2D (diameter and area) and 3D (lumen and vessel volume), with a workflow for determining the likely presence or absence of ischemia." https://cleerlyhealth.com/ (Ex. 29).



https://cleerlyhealth.com/ (Ex. 29)

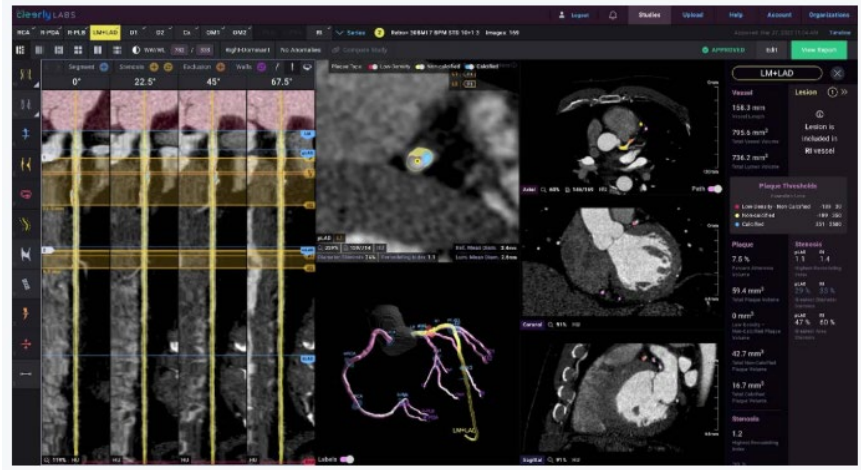


https://cleerlyhealth.com/what-is-cleerly (Ex. 41)

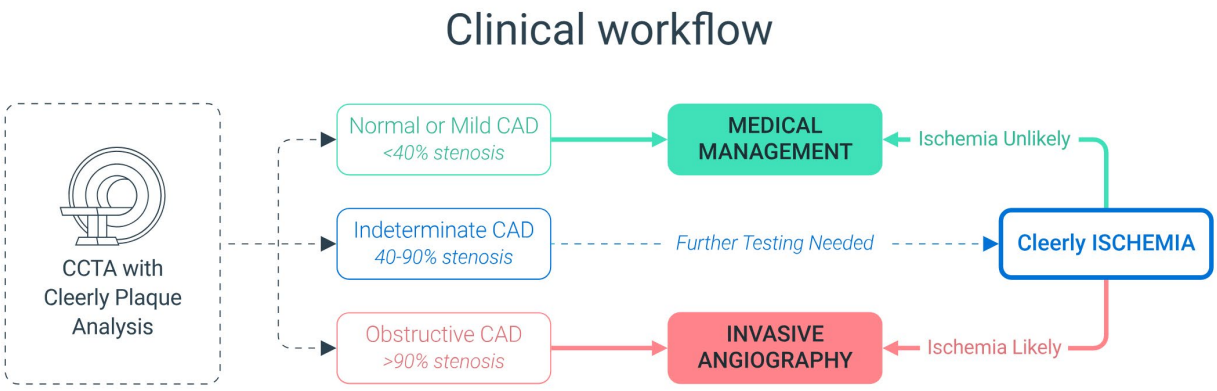
Cleerly uses proprietary and FDA-cleared machine learning algorithms to non-invasively measure atherosclerosis (plaque), stenosis, and likelihood of ischemia using coronary computed tomography angiography (CCTA) studies.

Our machine-learning AI generates a 3D model of the patient's coronary arteries, identifies their lumen and vessel walls, locates and measures stenoses, while quantifying and categorizing plaque.[1] Cleerly ISCHEMIA's algorithm uses measurements based on invasive FFR data to determine the likelihood of vessel-level ischemia.[2]

https://cleerlyhealth.com/what-is-cleerly (Ex. 41)

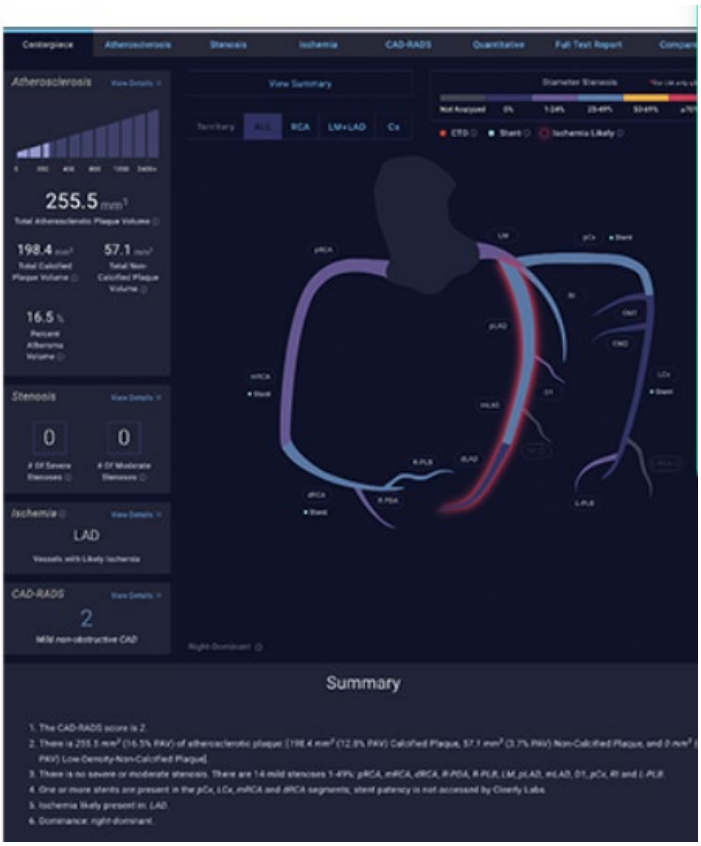


https://cleerlyhealth.com/what-is-cleerly (Ex. 41)

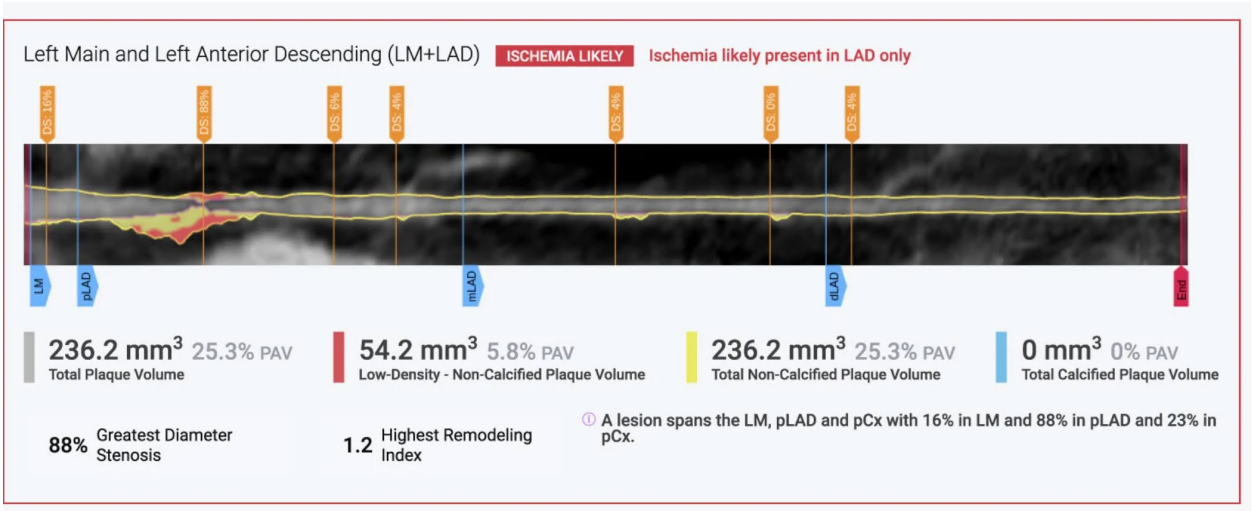


https://cleerlyhealth.com/ischemia-reinvented (Ex. 26)

https://cleerlyhealth.com/what-is-cleerly (Ex. 41)



https://cleerlyhealth.com/what-is-cleerly (Ex. 41)

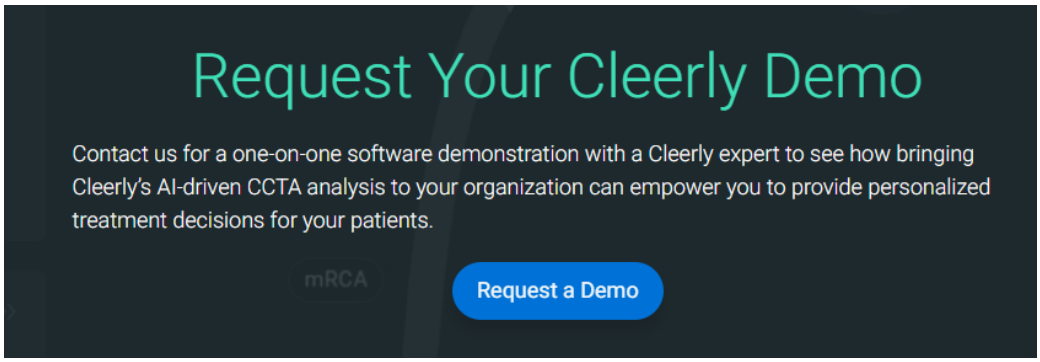


https://cleerlyhealth.com/patient-education (Ex. 35)

284. Heartflow reserves the right to discover and pursue any additional infringing products and services that incorporate infringing functionalities. For the avoidance of doubt, the

Accused '425 Cleerly Products are identified to describe Cleerly's infringement and in no way limit the discovery and infringement allegations against Cleerly concerning other products that incorporate the same or reasonably similar functionalities.

285. Upon information and belief, Cleerly directly infringes by performing one or more method claims in the United States when, for example, performing testing, including "usability tests" as confirmed in FDA submissions, generating tutorial videos for training purposes, training hospital employees, conducting webinars, conducting demos at events, and/or producing instructional videos showing how the Accused '425 Cleerly Products operate. https://www.youtube.com/@cleerlyhealth/videos (Ex. 42); https://cleerlyhealth.com/clinical-publications; https://cleerlyhealth.com/blog; https://cleerlyhealth.com/webinars; https://cleerlyhealth.com/events.



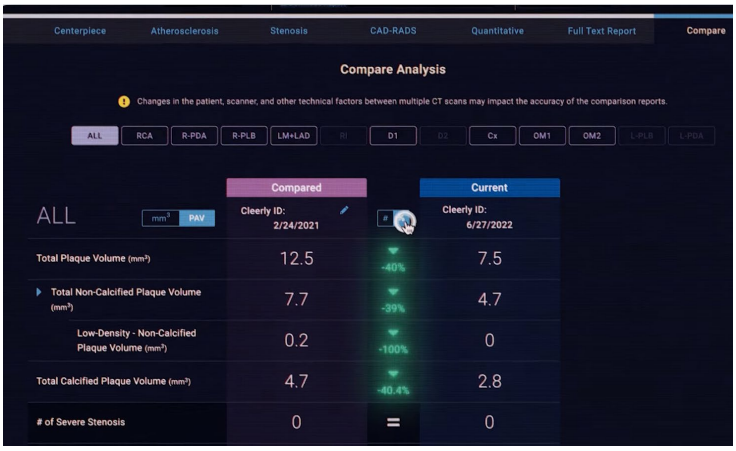
286. Each of the Accused '425 Cleerly Products, either alone or in combination with each other, perform a computer-implemented method or implement a system and/or computer-readable medium for personalized non-invasive assessment of artery stenosis for a patient.

287. For example, Cleerly Plaque Analysis receives noninvasively obtained CCTA medical image data of a patient's coronary arteries and extracts patient-specific arterial geometry by automatically generating centerlines and segmenting lumen and vessel walls to produce a 3D arterial model; it then derives quantitative features from that geometry, including plaque

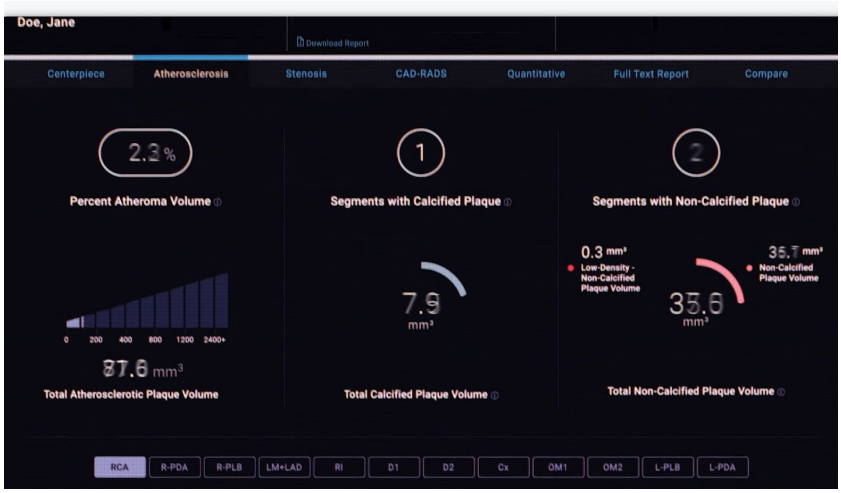
composition by Hounsfield Unit thresholds, vessel and lesion lengths and volumes, diameters and areas, stenosis severity, and remodeling index. *See* Ex. 48 (FDA 510(k) Premarket Notification K190868 (Cleerly Labs), https://www.accessdata.fda.gov/cdrh_docs/pdf19/K190868.pdf); Ex. 51 (CT Evaluation by Artificial Intelligence for Atherosclerosis, Stenosis and Vascular Morphology (CLARIFY), https://doi.org/10.1016/j.jcct.2021.05.004); Ex. 52 (Cleerly Coronary Plaque Analysis, https://cleerlyhealth.com/plaque-analysis).

288. Cleerly ISCHEMIA uses a trained machine-learning model to compute, for vessel locations of interest, a per-vessel ischemia index (CII) that applies a decision threshold explicitly equivalent to invasive FFR > 0.80 versus ≤ 0.80, thereby providing physiologic blood-pressure–related index values at clinically relevant locations. *See* Ex. 26 (Cleerly Non-Invasive Ischemia Analysis, https://cleerlyhealth.com/ischemia-reinvented) ("uses 37 measures of heart health to determine likelihood of coronary artery ischemia at a per-vessel level" with threshold equivalent to invasive FFR); Ex. 55 (FDA 510(k) Premarket Notification K231335 (Cleerly ISCHEMIA), https://www.accessdata.fda.gov/cdrh_docs/pdf23/K231335.pdf).

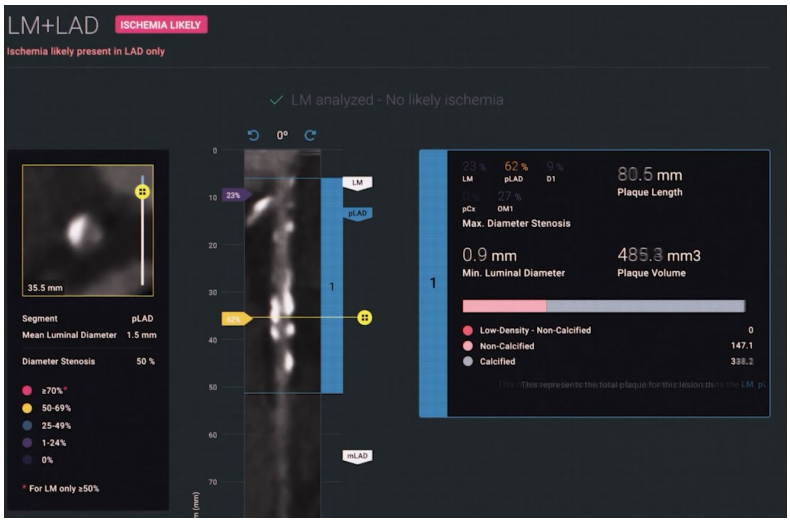
289. Each of the Accused '425 Cleerly Products, either alone or in combination with each other, generate numerous index values of physiologic values:



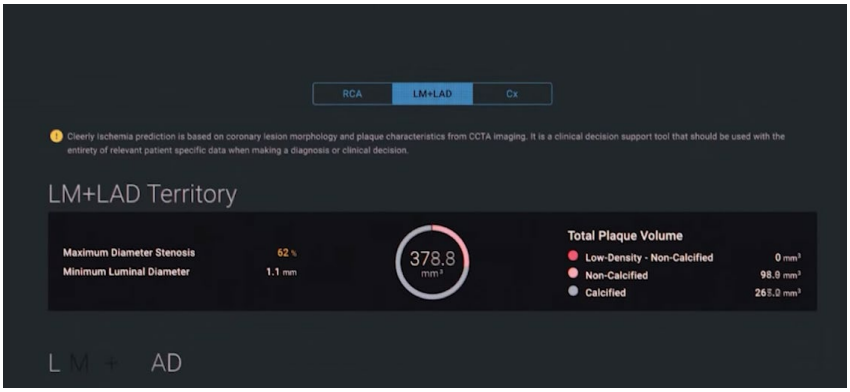
https://cleerlyhealth.com/ (Ex. 29)



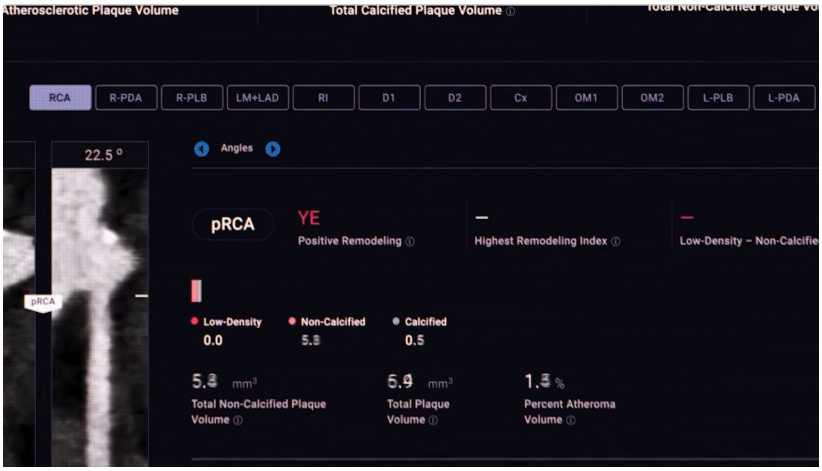
https://cleerlyhealth.com/ (Ex. 29)



Id.



Id.



Id.

290. At least Claim 5—which depends from Claim 1 and recites the limitations of Claim 1—requires receiving medical image data of at least a part of the patient's vascular system including one or more arteries of the patient. Upon information and belief, the Accused '425 Cleerly Products receive coronary computed tomography angiography (CCTA) image data of a patient's coronary arteries. Cleerly "uses proprietary and FDA-cleared machine learning algorithms to non-invasively measure atherosclerosis (plaque), stenosis, and likelihood of ischemia using coronary computed tomography angiography (CCTA) studies." Ex. 41 (What is Cleerly, https://cleerlyhealth.com/what-is-cleerly). CCTA images constitute medical image data of at least a part of the patient's vascular system, specifically the coronary arteries. Cleerly's platform is used to analyze "all major coronary arteries or branches" including those (≥1.5 mm). Ex. 43 (Griffin et al., AI Evaluation of Stenosis on Coronary CTA, Comparison With Quantitative Coronary Angiography and Fractional Flow Reserve: A CREDENCE Trial Substudy, https://www.jacc.org/doi/10.1016/j.jcmg.2021.10.020).

291. At least Claim 5 also requires extracting patient-specific arterial geometry of the patient from the received medical image data. The Accused '425 Cleerly Products include "machine-learning AI [that] generates a 3D model of the patient's coronary arteries, identifies their

lumen and vessel walls, locates and measures stenoses, while quantifying and categorizing plaque." Ex. 41 (What is Cleerly, https://cleerlyhealth.com/what-is-cleerly). For example, Cleerly's AI-QCT algorithm "first produces a centerline, lumen, and outer vessel wall contouring for every phase available and subsequently selects the 2 most optimal series for analysis." Ex. 62 (Nurmohamed et al., AI-Guided Quantitative Plaque Staging Predicts Long-Term Cardiovascular Outcomes, https://www.jacc.org/doi/10.1016/j.jcmg.2023.05.020). This centerline, lumen, and vessel wall contouring constitutes the patient-specific arterial geometry extracted from the received CCTA image data. In the CREDENCE trial substudy, Cleerly's software performed "automated analysis of coronary CTA using a series of validated convolutional neural network models (including VGG [Visual Geometry Group]-19 network, 3D U-Net, and VGG Network Variant) for image quality assessment, coronary segmentation and labeling, lumen wall evaluation and vessel contour determination, and plaque characterization." Ex. 43 (Griffin et al., https://www.jacc.org/doi/10.1016/j.jcmg.2021.10.020).

292. At least Claim 5 also requires extracting features from the patient-specific arterial geometry of the patient, the extracted features corresponding to features of a trained machine-learning based model for predicting physiologic values based on learned associations between the physiologic values and the extracted features. The Accused '425 Cleerly Products extracts quantitative features from the patient-specific arterial geometry. For Cleerly Plaque Analysis, these features include maximum stenosis diameter percentage, total calcified plaque, total non-calcified plaque, low-density plaque, lumen volume, total plaque, and plaque volume — all derived from the 3D coronary vessel model. Ex. 59 (Chiou et al., Artificial intelligence coronary computed tomography, coronary computed tomography angiography using fractional flow reserve, and physician visual interpretation in the per-vessel prediction of abnormal invasive adenosine

fractional flow reserve, https://pmc.ncbi.nlm.nih.gov/articles/PMC11195752/). For Cleerly ISCHEMIA, the platform extracts "37 parameters from the AI-QCT algorithm" that correspond to the features used in the trained machine-learning based ischemia model, which predicts the physiologic value of invasive FFR. *Id.* Additionally, the Accused '425 Cleerly Products provide "vessel-by-vessel detail" with "phenotyping for each artery and branch with stenosis quantification and vascular remodeling scores," further confirming that features are extracted at specific locations in the patient-specific arterial geometry. Ex. 52 (Cleerly Coronary Plaque Analysis, https://cleerlyhealth.com/plaque-analysis).

293. At least Claim 5 also requires automatically computing one or more index values of the physiologic values for one or more locations of interest in the patient-specific arterial geometry based on the extracted features using the trained machine learning based model trained based on features extracted from one or both of anatomical features extracted from individuals other than the patient and synthetically generated arterial geometries, based on the learned associations between physiologic values and the extracted features. The Accused '425 Cleerly Products' technology is "based on over 10 million images from over 40,000 patients gathered over a 15-year-period in landmark, multi-center clinical trials." Ex. 41 (What is Cleerly, https://cleerlyhealth.com/what-is-cleerly). The Cleerly ISCHEMIA algorithm was "developed and validated within the CREDENCE and PACIFIC study cohorts that included patients undergoing CCTA and used FFR of all coronary arteries as gold standard." Ex. 59 (Chiou et al., https://pmc.ncbi.nlm.nih.gov/articles/PMC11195752/). The patients in these training cohorts are necessarily individuals other than the patient being analyzed.

294. At least Claim 5 also requires that the model compute one or more index values of the physiologic values based on learned associations between physiologic values and the extracted

features. Cleerly ISCHEMIA uses "a random forest machine learning model" that was "developed using 37 parameters from the AI-QCT algorithm" to predict "invasive FFR ≤ 0.8 on a per-vessel basis." Ex. 59 (Chiou et al., https://pmc.ncbi.nlm.nih.gov/articles/PMC11195752/). The model was trained by relating the 37 quantitative features (extracted from the arterial geometry) to invasive FFR values (the physiologic values) measured in the CREDENCE and PACIFIC trial cohorts, generating learned associations between those features and the physiologic values. *Id.* The '425 Patent describes FFR as an index value that the claimed method can be used to compute.

295. At least Claim 5 also requires automatically computing one or more index values of the physiologic values for one or more locations of interest in the patient-specific arterial geometry. Cleerly ISCHEMIA automatically outputs "a CLEERLY ISCHEMIA Index (CII), a binary indication of likely ischemia regarding presence vs. absence for a given vessel, which is equivalent to invasive FFR ≤ 0.80 vs. > 0.80." Ex. 59 (Chiou et al., https://pmc.ncbi.nlm.nih.gov/articles/PMC11195752/). The CII constitutes an index value of a physiologic value (FFR) computed for one or more locations of interest (each coronary vessel) in the patient-specific arterial geometry. This computation is performed automatically: vessels with "AI-QCT-determined stenosis ≤ 20% were automatically considered non-ischemic, and vessels with AI-QCT-determined stenosis > 80% were automatically considered ischaemic. For the remaining vessels, a random forest machine learning model" was applied. *Id.*

296. Cleerly ISCHEMIA "uses 37 measures of heart health to determine likelihood of coronary artery ischemia at a per-vessel level" using "machine learning." Ex. 26 (Cleerly Non-Invasive Ischemia Analysis, https://cleerlyhealth.com/ischemia-reinvented). For Cleerly Plaque Analysis, the platform automatically computes quantitative index values including maximum stenosis diameter percentage, plaque volumes by composition, percentage atheroma volume, and

vascular remodeling index at specific locations in the patient-specific arterial geometry, all derived from the trained machine-learning models. Ex. 52 (Cleerly Coronary Plaque Analysis, https://cleerlyhealth.com/plaque-analysis); Ex. 57 (Cleerly Atherosclerosis, Stenosis and Ischemia Analysis, https://cleerlyhealth.com/diagnosing-cad).

297. At least Claim 5 also requires extracting a plurality of geometric measurements for one or more artery stenosis regions in the patient-specific arterial geometry of the patient. The Accused '425 Cleerly Products extract such measurements: vessels with "AI-QCT-determined stenosis ≤ 20% were automatically considered non-ischemic, and vessels with AI-QCT-determined stenosis > 80% were automatically considered ischemic. For the remaining vessels, a random forest machine learning model" was applied. Ex. 59 (Chiou et al., https://pmc.ncbi.nlm.nih.gov/articles/PMC11195752/).

298. Additional evidence of the Accused '425 Cleerly Products infringing Claims 5-10, 15-17, and 20 is included in the documents below, including representations Cleerly made in its FDA filings and details Cleerly disclosed about techniques it implements in the Accused '425 Cleerly Products in articles and appendices attached to the articles.

299. For example, an FDA submission dated September 22, 2020 includes representations by Cleerly that provide evidence of the Accused '425 Cleerly Products infringing one or more claims of the '425 Patent, including implementing machine learning along with receiving medical image data, extracting patient-specific arterial geometry and features from the patient-specific arterial geometry, computing one or more index values of the physiologic values, and extracting a plurality of geometric measurements for stenosis regions in the patient-specific arterial geometry of the patient.

Device Name

Cleerly ISCHEMIA

Indications for Use *(Describe)*

Cleerly ISCHEMIA analysis software is an automated machine learning-based decision support tool, indicated as a diagnostic aid for patients undergoing CT analysis using Cleerly Labs software. When utilized by an interpreting healthcare provider, this software tool provides information that may be useful in detecting likely ischemia associated with coronary artery disease. Patient management decisions should not be made solely on the results of the Cleerly ISCHEMIA analysis.

Ex. 55 (FDA 510(k) Summary for Cleerly ISCHEMIA (K231335), https://www.accessdata.fda.gov/cdrh_docs/pdf23/K231335.pdf).

4. Device Description

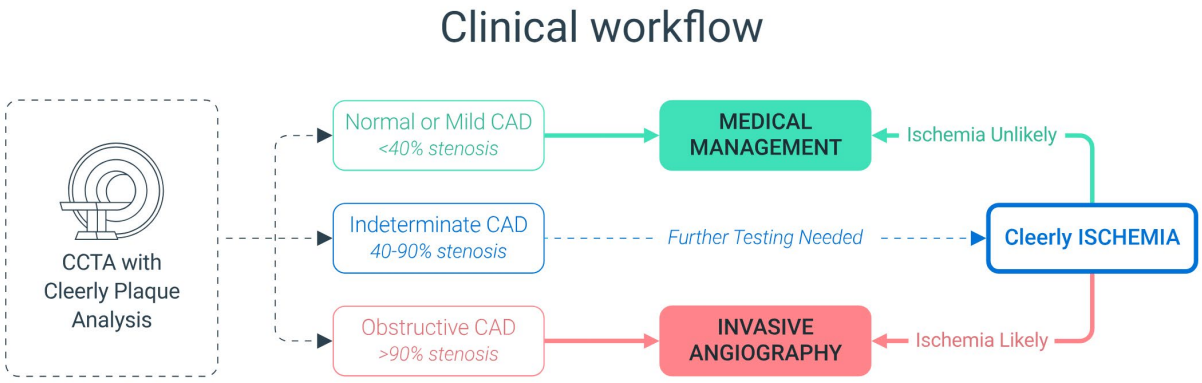
Cleerly ISCHEMIA is an add-on software module to Cleerly Labs (K202280, K190868) that determines the likely presence or absence of coronal vessel ischemia based on quantitative measures of atherosclerosis, stenosis, and significant vascular morphology from typically-acquired Coronary Computed Tomography Angiography images (CCTA). Cleerly ISCHEMIA, in conjunction with Cleerly Labs, outputs a Cleerly ISCHEMIA Index (CII), a binary indication of negative CII (likely absence of ischemia) or positive CII (likely presence of ischemia) with its threshold equivalent to invasive FFR >0.80 vs. ≤0.80, respectively, as identified in professional societal practice guidelines.

Id.

The Cleerly ISCHEMIA data workflow begins after the Cleerly Labs outputs are approved for a study. A pre-processing module evaluates the eligibility of a study or vessels within the study for the Cleerly ISCHEMIA algorithm. The presence of certain identified anomalies can make an entire study ineligible, whereas the presence of a stent or exclusion in a vessel can make just that vessel ineligible. For all eligible vessels within a study, relevant Cleerly Labs outputs are aggregated from the default segment level to vessel level as the inputs to the Cleerly ISCHEMIA algorithm to determine the likely presence of ischemia. The results will then be evaluated by a post-processing module, which ensures that vessels subtended to a likely ischemic vessel are also marked as likely ischemic. The Cleerly ISCHEMIA algorithm outputs a Cleerly ISCHEMIA Index (CII), a binary indication of likely ischemia presence vs absence for a given vessel, which is equivalent to invasive FFR ≤0.80 vs. >0.80, respectively. Invasive FFR is a widely accepted gold-standard for determining vessel-specific ischemia. The Cleerly ISCHEMIA algorithm is "locked," meaning it is not a continuous learning algorithm.

Cleerly ISCHEMIA Index (likely ischemia / not likely ischemia) is displayed visually by Cleerly Labs to show the likely presence or absence of ischemia within epicardial coronary artery vessels. Vessels with Cleerly ISCHEMIA Index indicating likely ischemia presence (positive CII) are illuminated red, while vessels with Cleerly ISCHEMIA Index indicating likely ischemia absence (negative CII) are not illuminated. Cleerly ISCHEMIA analysis is intended to non-invasively support the functional evaluation of clinically stable symptomatic patients with coronary artery disease (CAD).

Id.



Ex. 26 (Cleerly Non-Invasive Ischemia Analysis, https://cleerlyhealth.com/ischemia-reinvented)

Cleerly Labs provides a visualization of the Cleerly Labs analysis in the CORONARY Report. The CORONARY Report uses data previously acquired from the Cleerly Labs image analysis to generate a visually interactive and comprehensive report that details the atherosclerosis and stenosis findings of the patient. This report is not intended to be the final report (i.e., physician report) used in patient diagnosis and treatment. Cleerly Labs provides the ability to send the text report page of the CORONARY Report to the user's PACS system.

Cleerly 510(k) Summary, K202280, September 22, 2020 (Ex. 47)

6. Software Functionality

In Cleerly Labs, users can edit the lumen and vessel walls of the suggested segmentation, and demarcate stenosis and stents, to more efficiently perform coronary analysis. Users are provided with navigation and editing/visualization tools to aid in image analysis. Plaque (i.e., atherosclerosis) and stenosis measurements are outputted based on the fully user-editable segmentation of the coronary artery. The user is also provided with the ability to indicate coronary anatomical findings.

Following the completion of study analysis, an interactive CORONARY Report is generated (the subject device of this submission). The CORONARY Report summarizes the analysis data from Cleerly Labs by reporting them as findings on atherosclerosis and stenosis, which may be used as supporting data in the evaluation of CAD. Components of the CORONARY Report include data visualization and reporting features. **Table 4** below compares the key features of the subject and predicate devices.

Id.

300. An additional FDA submission dated October 9, 2019 includes representations by Cleerly that also provide evidence of the Accused '425 Cleerly Products infringing one or more claims of the '425 Patent:

Device Description

Cleerly Labs is a post-processing web-based software application that enables trained medical professionals to analyze 2D/3D coronary images acquired from Computed Tomography (CT) angiographic scans. The software is a post-processing tool that aids in determining treatment paths for patients suspected to have coronary artery disease (CAD).

The output of the software includes visual images of coronary arteries, distance and volume measurements of the lumen wall, vessel wall, and plaque, remodeling index as well as stenosis diameter and area. These measurements are based on user segmentation.

Cleerly 510(k) Summary, K190868, October 9, 2019 (Ex. 48)

- A Usability test was conducted with U.S. board certified radiologists and technicians to ensure the clinical acceptability of the device.
- The machine learning algorithms were evaluated by comparing the output of the software to that of the ground truth using multiple ground truthers.

Id.

Visualization / Edit Tools	• Lumen Wall • Vessel Wall • Segment • Stenosis • Centerline • Plaque • Chronic Total Occlusion (CTO) • Stent • Exclude • Distance
2D Imaging	Yes
3D Imaging	Yes
Multiplanar Reformat (MPR)	Yes
Segmentation of region of interest	Manual and Semi-Automatic

Quantification	
Hounsfield Unit (HU)	Yes
Distance Measurements	• Vessel • Lesion • Length
Volumetric Measurements	• Total Vessel • Total Lumen • Non-Calcified Plaque (NCP) • Low-Density Non-Calcified Plaque (LD-NCP) • Calcified Plaque (CP) • Total Plaque
Remodeling Index	Yes
Stenosis	• % Area Stenosis • % Diameter Stenosis

Id.

Cleerly Labs utilizes machine learning and simple rule-based mathematical calculation components which are performed on the backend of the software. The software applies deep learning methodology to identify high quality images, segment and label coronary arteries, and segment lumen and vessel walls. 2D and 3D images are presented to the user for review and manual editing. This segmentation is designed to improve efficiency for the user, and help shorten tedious, time-consuming manual tasks.

Cleerly Labs provides a visualization of the Cleerly Labs analysis in the CORONARY Report. The CORONARY Report uses data previously acquired from the Cleerly Labs image analysis to generate a visually interactive and comprehensive report that details the atherosclerosis and stenosis findings of the patient. This report is not intended to be the final report (i.e., physician report) used in patient diagnosis and treatment. Cleerly Labs provides the ability to send the text report page of the CORONARY Report to the user's PACS system.

Id.

6. Software Functionality

In Cleerly Labs, users can edit the lumen and vessel walls of the suggested segmentation, and demarcate stenosis and stents, to more efficiently perform coronary analysis. Users are provided with navigation and editing/visualization tools to aid in image analysis. Plaque (i.e., atherosclerosis) and stenosis measurements are outputted based on the fully user-editable segmentation of the coronary artery. The user is also provided with the ability to indicate coronary anatomical findings.

Following the completion of study analysis, an interactive CORONARY Report is generated (the subject device of this submission). The CORONARY Report summarizes the analysis data from Cleerly Labs by reporting them as findings on atherosclerosis and stenosis, which may be used as supporting data in the evaluation of CAD. Components of the CORONARY Report include data visualization and reporting features. **Table 4** below compares the key features of the subject and predicate devices.

Id.

301. Further, upon information and belief, the functionality of the Accused '425 Cleerly Products is described in the paper titled "CT Evaluation by Artificial Intelligence for Atherosclerosis, Stenosis and Vascular Morphology (CLARIFY): A Multi-center, international study" (Ex. 51), which also provides additional evidence that the Accused '425 Cleerly Products infringe one or more claims of the '425 Patent:

Artificial Intelligence Segmentation and Plaque Quantification. CCTA studies were uploaded to and analyzed by FDA-cleared software Cleerly LABS (Cleerly, New York, New York).[17,18] The three sites contributing cases were not used for software development or validation. This study is an investigator initiated study and Cleerly had no role in the study design or performance. Cleerly performed AI-aided CCTA analyses for the study in a blinded manner, and provided statistical services as determined and requested by study investigators.

This is an AI-aided approach (**Central Illustration**) that performs automated analysis of CCTA using a series of validated convolutional neural network models (including VGG 19 network, 3D U-Net and VGG Network Variant) for image quality assessment, coronary segmentation and labeling, lumen wall evaluation and vessel contour determination and plaque characterization.[10,19] A full graphical representation of the algorithm with validation details is presented in Appendix B. First, the AI-aided approach leverages 2 deep convolutional neural networks to

Id.

L3 readers determined maximum diameter stenosis was compared with AI stenosis on a per-patient and per-vessel basis. Correlation and numeric agreement were assessed. The Pearson correlation coefficient was used to evaluate correlation, linear regression plots were generated for visualization of the relationship. Bland-Altman plots with limits of agreement was performed. Diagnostic performance of AI vs L3 was assessed through diagnostic accuracy, sensitivity, specificity, positive and negative predictive values at both >50% and >70% stenosis thresholds on per vessel and per patient basis.

Id.

Readers determined presence of two high risk plaque features—low attenuation plaque <30 Hounsfield units (HU) and positive arterial remodeling with a remodeling index ≥1.10 by diameter—with this analysis compared with AI on per vessel and per patient basis. This binary outcome was compared by calculating the percent agreement and kappa statistic.

Id.

302. The foregoing features and capabilities of each of the Accused '425 Cleerly Products description and/or demonstration thereof, including in advertising, reflect Cleerly's direct infringement by satisfying every element of at least Claims 5-10, 15-17, and 20 of the '425 Patent under 35 U.S.C. § 271(a).

303. Upon information and belief, Cleerly has induced infringement, and continues to induce infringement, of one or more Claims 5-10, 15-17, and 20 of the '425 Patent by actively and knowingly inducing others, including health care providers and hospitals in the Eastern District of Texas and throughout the United States, to directly infringe one or more claims of the '425 Patent through the use of Cleerly's products and services. For example, Cleerly instructs hospital employees and doctors, and induces patients through its website, via generating tutorial videos for training purposes, training hospital employees, conducting webinars, conducting demos at events, and/or producing instructional videos to induce them to directly infringe one or more claims of the '425 Patent through the use of the Accused '425 Cleerly Products. *See* https://www.youtube.com/@cleerlyhealth/videos (Ex. 42); https://cleerlyhealth.com/clinical-

publications; https://cleerlyhealth.com/blog; https://cleerlyhealth.com/webinars; https://cleerlyhealth.com/events.

304. Upon information and belief, Cleerly has contributed to the infringement of one or more Claims 5-10, 15-17, and 20 of the '425 Patent by providing products and services that constitute material parts of the claimed inventions, knowing the same to be especially made or adapted for use in an infringing manner. For example, the Accused '425 Cleerly Products include at least one component to generate images and implement CNN to be used in conjunction with the Cleerly Platform to perform CAD detection. This is a component of a patented machine, manufacture, or combination, or an apparatus for use in practicing a patented process. Furthermore, such component is a material part of the invention and upon information and belief is not a staple article or commodity of commerce suitable for substantial non-infringing use. Thus, Cleerly is liable for infringement of the '425 Patent pursuant to 35 U.S.C. § 271(c).

305. Upon information and belief, Cleerly has been on notice of the '425 Patent at least since its issuance, and Cleerly's infringement of the '425 Patent has been and continues to be willful. For example, Cleerly, through its founder, Dr. James K. Min, had actual knowledge of Heartflow's patent portfolio through Dr. Min's role as a Heartflow consultant from 2012 to 2017, his execution of an NDA and Consulting Agreement with Heartflow, and his role as lead investigator on Heartflow's DeFACTO study. Dr. Min incorporated Cleerly on July 19, 2016 while still subject to the Consulting Agreement and its confidentiality, non-compete, and invention assignment obligations. Cleerly further acquired actual knowledge of Heartflow's patents through its hiring of Brent Ness, Heartflow's former Chief Commercial Officer, who was bound by confidentiality obligations under the Ness Agreement and Separation Agreement. Cleerly has

knowledge about the ’425 Patent based on Cleerly citing the ’425 Patent repeatedly in its own patents as seen below:

Heartflow’s Patent	**Cleerly Patent Citing Heartflow’s Patent**
US11,013,425B2	US 11,113,811 B2 US 11,210,786 B2 US 11,317,883 B2 US 11,861,833 B2 US 11,922,627 B2 US 12,144,669 B2 US 12,380,560 B2 US 12,440,180 B2 US 12,558,048 B2

306. By the time of trial, Cleerly will thus have known and intended (since receiving such notice), that its continued actions would actively induce and contribute to actual infringement of one or more Claims 5-10, 15-17, and 20 of the ’425 Patent.

307. Despite this actual knowledge of Heartflow’s patents, Cleerly deliberately chose to develop and commercialize infringing products rather than seek a license of those patents.

308. Cleerly undertook and continues its infringing actions despite an objectively high likelihood that such activities infringed the ’425 Patent, which has been duly issued by the USPTO and is presumed valid. For example, Cleerly has been aware of an objectively high likelihood that its actions constituted, and continue to constitute, infringement of the ’425 Patent based on Dr. Min’s actual knowledge and Cleerly’s knowledge as shown on Cleerly’s own patents, and that the ’425 Patent is valid. On information and belief, Cleerly cannot reasonably, subjectively believe that its actions do not constitute infringement of the ’425 Patent, nor could it reasonably, subjectively believe that the patent is invalid. Despite that knowledge and subjective belief, and the objectively high likelihood that its actions constitute infringement, Cleerly has continued its infringing activities. As such, Cleerly willfully infringes the ’425 Patent.

309. Heartflow has been damaged by Cleerly's infringement of the '425 Patent and is entitled to recover damages adequate to compensate for such infringement pursuant to 35 U.S.C. § 284.

DAMAGES

310. As a result of Cleerly's acts of infringement, Heartflow has suffered actual and consequential damages, including lost profits. Heartflow and Cleerly are direct competitors in the cardiac diagnostic market, offering substantially similar products to the same health care providers and patients. Heartflow's patented technology satisfies the demand for noninvasive coronary artery disease diagnostics, and upon information and belief, absent Cleerly's infringing products, Heartflow would have made additional sales and earned additional revenue. The market for CCTA analysis platforms is highly concentrated, with Heartflow and Cleerly as the principal competitors. Upon information and belief, there are no acceptable non-infringing alternatives that provide the same combination of plaque analysis, stenosis quantification, and ischemia assessment from CCTA images. To the fullest extent permitted by law, Heartflow seeks recovery of damages, including lost profits, and in no event less than a reasonable royalty.

311. To the extent required, Heartflow has complied with the marking and notice requirements of 35 U.S.C. § 287. To the extent any of the Asserted Patents include method claims, the marking requirement of Section 287 is inapplicable to such claims. To the extent the marking requirement applies, Heartflow has provided actual notice to Cleerly of its infringement, and as shown above, Cleerly had actual knowledge of the Asserted Patents and its infringement thereof.

312. Unless enjoined, Cleerly will continue to infringe the Asserted Patents, causing Heartflow irreparable harm for which monetary damages alone are an inadequate remedy. Heartflow and Cleerly are direct competitors, and Cleerly's continued sale of infringing products directly erodes Heartflow's market position, diverts customers and revenue, and undermines

Heartflow's ability to recoup its substantial investment in research and development. The balance of hardships weighs in Heartflow's favor because Cleerly built its competing platform by leveraging technology and confidential information derived from Heartflow's innovation and protected by Heartflow's patents. The public interest favors an injunction because it would vindicate the patent system's fundamental purpose of incentivizing innovation and protecting inventors' exclusive rights.

JURY TRIAL DEMANDED

Heartflow hereby demands a trial by jury.

PRAYER FOR RELIEF

WHEREFORE, Heartflow prays for relief as follows:

- A judgment declaring that Cleerly has infringed and is infringing one or more claims of the '813, '569, '303, '399, '386, and '425 Patents;
- A judgment awarding Heartflow damages as a result of Cleerly's infringement of one or more claims of the '813, '569, '303, '399, '386, and '425 Patents, together with interest and costs, consistent with lost profits and in no event less than a reasonable royalty;
- A judgment awarding Heartflow treble damages and pre-judgment interest under 35 U.S.C. § 284 as a result of Cleerly's willful and deliberate infringement of one or more claims of the '813, '569, '303, '399, '386, and '425 Patents;
- A judgment declaring that this case is exceptional and awarding Heartflow its expenses, costs, and attorneys' fees in accordance with 35 U.S.C. §§ 284 and 285 and Rule 54(d) of the Federal Rules of Civil Procedure;
- A grant of a permanent injunction enjoining Cleerly from further acts of infringement of one or more claims of the '813, '569, '303, '399, '386, and '425 Patents; and

- Such other and further relief as the Court deems just and proper.

Dated: April 13, 2026

Respectfully submitted,

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