Circle Cardiovascular Imaging Inc.
Omar Naimi
Regulatory Affairs & Quality Management Systems Analyst
Suite 1800, 707 8 Avenue SW
Calgary, AB T2P 1H5
Canada

October 27, 2025

Re: K251027
Trade/Device Name: cvi42 Coronary Plaque Software Application
Regulation Number: 21 CFR 892.2050
Regulation Name: Medical Image Management And Processing System
Regulatory Class: Class II
Product Code: QIH
Dated: September 25, 2025
Received: September 26, 2025

Dear Omar Naimi:

We have reviewed your section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (the Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database available at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR Part 803) for devices or postmarketing safety reporting (21 CFR Part 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn

(https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Jessica Lamb, Ph.D.
Assistant Director
DHT8B: Division of Radiological Imaging
Devices and Electronic Products
OHT8: Office of Radiological Health
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K251027

Device Name
cvi42 Coronary Plaque Software Application

Indications for Use *(Describe)*
cvi42 Coronary Plaque Software Application is intended to be used for viewing, post-processing, qualitative and quantitative evaluation of cardiovascular computed tomography (CT) images in a Digital Imaging and Communications in Medicine (DICOM) Standard format.

It enables a set of tools to assist physicians in qualitative and quantitative assessment of cardiac CT images to determine the presence and extent of coronary plaques and stenoses, in patients who underwent Coronary Computed Tomography Angiography (CCTA) for evaluation of CAD or suspected CAD.

cvi42 Coronary Plaque's semi-automated machine learning algorithms are intended for an adult population.

cvi42 Coronary Plaque shall be used only for cardiac images acquired from a CT scanner. It shall be used by qualified medical professionals, experienced in examining cardiovascular CT images, for the purpose of obtaining diagnostic information as part of a comprehensive diagnostic decision-making process.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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Coronary Plaque Module 510(k) Summary

The following 510(k) summary of safety and effectiveness information is submitted in accordance with the requirements of the Safe Medical Device Act 1990 and 21 CFR 807.92(c).

I. SUBMITTER

Submitter's Name:	Circle Cardiovascular Imaging, Inc.
Address:	Suite 1800 – 707 8th Ave SW, Calgary, AB, Canada, T2P 1H5
Date Prepared:	October 27, 2025
Telephone Number:	+1 587 686 0784
Contact Person :	Omar Naimi
Email:	omar.naimi@circlecvi.com

II. DEVICE

510(k)	K251027
Name of the Device:	cvi42 Coronary Plaque Software Application
Common or Usual Name:	Radiological Image Processing System
Classification Name:	Medical Image Management and Processing System
Proposed Classification:	Device Class: II Product Code: QIH, LLZ Regulation Number: 21 CFR 892.2050

III. PREDICATE DEVICE

The predicate device(s) identified are cvi42 Auto Imaging Software Application manufactured by Circle Cardiovascular Imaging Inc. (K213998) as the primary predicate, and Cleerly Labs manufactured by Cleerly Inc. (K190868) as the secondary predicate.

The predicate device(s) have not been subject to a design-related recall.

IV. DEVICE DESCRIPTION

Circle's cvi42 Coronary Plaque Software Application ('cvi42 Coronary Plaque' or 'Coronary Plaque Module', for short) is a Software as a Medical Device (SaMD) that enables the analysis of CT Angiography scans of the coronary arteries of the heart. It is designed to support physicians in the visualization, evaluation, and analysis of coronary vessel plaques through manual or semi-automatic segmentation of vessel lumen and wall to determine the presence and extent of coronary plaques and luminal stenoses, in patients who underwent Coronary Computed Tomography Angiography (CCTA) for the evaluation of coronary artery disease (CAD) or suspected CAD. The device is intended to be used as an aid to the existing standard of care and does not replace existing software applications that physicians use. The Coronary Plaque Module can be integrated into an image viewing software intended for visualization of cardiac images, such as Circle's FDA-cleared cvi42 Software Application. The Coronary Plaque Module does not interface directly with any data collection equipment, and its functionality is independent of the type of vendor acquisition equipment. The analysis results are available on-screen, can be sent to report or saved for future review.

The Coronary Plaque Module consists of multiplanar reconstruction (MPR) views, curved planar reformation (CPR) and straightened views, and 3D rendering of the original CT data. The Module displays three orthogonal MPR views that the user can freely adjust to any position and orientation. Lines and regions of interest (ROIs) can be manually drawn on these MPR images for quantitative measurements.

The Coronary Plaque Module implements an Artificial Intelligence/Machine Learning (AI/ML) algorithm to detect lumen and vessel wall structures. Further, the module implements post-processing methods to convert coronary artery lumen and vessel wall structures to editable surfaces and detect the presence and type of coronary plaque in the region between the lumen and vessel wall. All surfaces generated by the system are editable and users are advised to verify and correct any errors.

The device allows users to perform the measurements listed in **Table 1**.

Coronary Plaque Module 510(k) Summary

Table 1. Measurements in the Coronary Plaque Module

Measurement [units]	Description	Display
Calcified Plaque (CP) Volume [mm^3]	The volume of calcified plaque (CP) in a lesion or all the lesions in a vessel.	• On Screen Data Panel • Coronaries (Plaque) Module Report
Non-Calcified Plaque (NCP) Volume [mm^3]	The volume of non-calcified plaque (NCP) in a lesion or all the lesions in a vessel.	• On Screen Data Panel • Coronaries (Plaque) Module Report
Low-Attenuation Plaque (LAP) Volume [mm^3]	The volume of low-attenuation plaque (LAP) in a lesion or all the lesions in a vessel; LAP volume is also included in NCP volume.	• On Screen Data Panel • Coronaries (Plaque) Module Report
Total Plaque Volume [mm^3]	The volume of total plaque including CP and NCP (with LAP) in a lesion or all the lesions in a vessel.	• On Screen Data Panel • Coronaries (Plaque) Module Report
Calcified Plaque (CP) Burden [%]	The burden of CP in a lesion or the whole vessel; obtained by dividing the CP volume by the lesion vessel wall or entire vessel volume, as appropriate.	• On Screen Data Panel • Coronaries (Plaque) Module Report
Non-Calcified Plaque (NCP) Burden [%]	The burden of NCP in a lesion or the whole vessel; obtained by dividing the NCP volume by the lesion vessel wall or entire vessel volume, as appropriate.	• On Screen Data Panel • Coronaries (Plaque) Module Report
Low-Attenuation Plaque (LAP) Burden [%]	The burden of LAP in a lesion or the whole vessel; obtained by dividing the LAP volume by the lesion vessel wall or entire vessel volume, as appropriate.	• On Screen Data Panel • Coronaries (Plaque) Module Report
Total Plaque Burden [%]	The burden of total plaque in a lesion or the whole vessel; obtained by dividing the total plaque volume by the lesion vessel wall or entire vessel volume, as appropriate.	• On Screen Data Panel • Coronaries (Plaque) Module Report
Remodeling Index [no unit]	A measure of enlargement of vessel dimensions to accommodate plaque development compared to normal vessel sections; it is expressed as the ratio of the largest diameter across the lesion and reference diameter (or maximum vessel wall cross-sectional area and reference vessel wall cross-sectional area).	• On Screen Data Panel • Coronaries (Plaque) Module Report
Diameter-Based Stenosis [%]	Stenosis expressed as the percent amount of reduced lumen diameter compared with reference diameter.	• On Screen Data Panel • Coronaries (Plaque) Module Report
Area-Based Stenosis [%]	Stenosis expressed as the percent amount of reduced lumen area compared with reference area.	• On Screen Data Panel • Coronaries (Plaque) Module Report
Lesion Length [mm]	The length of the lesion.	• On Screen Data Panel • Coronaries (Plaque) Module Report

V. INTENDED USE / INDICATIONS FOR USE

Intended Use

Viewing, post-processing, qualitative and quantitative evaluation of blood vessels and cardiovascular CT images in DICOM format.

Indications for Use

cvi42 Coronary Plaque Software Application is intended to be used for viewing, post-processing, qualitative and quantitative evaluation of cardiovascular computed tomography (CT) images in a Digital Imaging and Communications in Medicine (DICOM) Standard format.

It enables a set of tools to assist physicians in qualitative and quantitative assessment of cardiac CT images to determine the presence and extent of coronary plaques and stenoses, in patients who underwent Coronary Computed Tomography Angiography (CCTA) for evaluation of CAD or suspected CAD.

cvi42 Coronary Plaque's semi-automated machine learning algorithms are intended for an adult population.

cvi42 Coronary Plaque shall be used only for cardiac images acquired from a CT scanner. It shall be used by qualified medical professionals, experienced in examining cardiovascular CT images, for the purpose of obtaining diagnostic information as part of a comprehensive diagnostic decision-making process.

VI. COMPARISON WITH PREDICATE DEVICE

The detailed analysis of the subject device and the predicate devices (shown in **Table 2** and **Table 3**) demonstrates that the subject device is substantially equivalent in indications for use / intended use, technological characteristics, functionality, and operating principles with the primary (K213998) and secondary (K190868) predicates. Of the three characteristics (technical, biological, and clinical) required for the demonstration of equivalence, biological characteristics are not applicable since both the subject device and predicate device(s) are software as a medical device applications with no tangible component interfacing with the body.

Table 2. Intended use and indications comparison.

	Subject Device *cvi42 Coronary Plaque Software Application* Manufactured by Circle Cardiovascular Imaging Inc.	**Primary Predicate** *cvi42 Auto Imaging Software Application (K213998)* Manufactured by Circle Cardiovascular Imaging Inc.	**Secondary Predicate** *Cleerly Labs (K190868)* Manufactured by Cleerly Inc.
Intended Use	Viewing, post-processing, qualitative and quantitative evaluation of blood vessels and cardiovascular CT images in DICOM format.	Viewing, post-processing, qualitative and quantitative evaluation of blood vessels and cardiovascular MR and CT images in DICOM format.	N/A
Indications for Use	cvi42 Coronary Plaque Software Application is intended to be used for viewing, post-processing, qualitative and quantitative evaluation of cardiovascular computed tomography (CT) images in a Digital Imaging and Communications in Medicine (DICOM) Standard format. It enables a set of tools to assist physicians in qualitative and quantitative assessment of cardiac CT images to determine the presence and extent of coronary plaques and stenoses, in patients who underwent Coronary Computed Tomography Angiography (CCTA) for evaluation of CAD or suspected CAD. cvi42 Coronary Plaque's semi-automated machine learning algorithms are intended for an adult population. cvi42 Coronary Plaque shall be used only for cardiac images acquired from a CT scanner. It shall be used by qualified medical professionals, experienced in examining cardiovascular CT images, for the purpose of obtaining diagnostic information as part of a comprehensive diagnostic decision-making process.	cvi42 Auto is intended to be used for viewing, post-processing, qualitative and quantitative evaluation of cardiovascular magnetic resonance (MR) and computed tomography (CT) images in a Digital Imaging and Communications in Medicine (DICOM) Standard format. It enables a set of tools to assist physicians in qualitative assessment of cardiac images and quantitative measurements of the heart and adjacent vessels; perform calcium scoring; and to confirm the presence or absence of physician-identified lesion in blood vessels. The target population for cvi42 Auto's manual workflows is not restricted; however, cvi42 Auto's semi-automated machine learning algorithms are intended for an adult population. cvi42 Auto shall be used only for cardiac images acquired from an MR or CT scanner. It shall be used by qualified medical professionals, experienced in examining and evaluating cardiovascular MR or CT images, for the purpose of obtaining diagnostic information as part of a comprehensive diagnostic decision-making process.	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 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. The software is not intended to replace the skill and judgment of a qualified medical practitioner and should only be used by people who have been appropriately trained in the software's functions, capabilities and limitations. Users should be aware that certain views make use of interpolated data. This is data that is created by the software based on the original data set. Interpolated data may give the appearance of healthy tissue in situations where pathology that is near or smaller than the scanning resolution may be present.

Table 3. Regulatory and technological features comparison.

Feature	**Subject Device** *Coronary Plaque Module* Manufactured by Circle Cardiovascular Imaging Inc.	**Primary Predicate** *cvi42 Auto (K213998)* Manufactured by Circle Cardiovascular Imaging Inc.	**Secondary Predicate** *Cleerly Labs (K190868)* Manufactured by Cleerly Inc	**Comparison**
Device Class	II	II	II	Same as predicate device(s)
Product Code	QIH, LLZ	QIH, LLZ	LLZ	Same as primary predicate device, secondary predicate uses AI/ML functionality.
Regulation Name	Medical image management and processing system	Medical image management and processing system	Picture archiving and communications system	Same as primary predicate device, secondary predicate uses AI/ML functionality.
Regulation Number	21 CFR § 892.2050	21 CFR § 892.2050	21 CFR § 892.2050	Same as predicate device(s)
Computer operating system	macOS, Microsoft Windows	macOS, Microsoft Windows	Client-Server Google Chrome Application	Same as primary predicate device. Core functionality of subject device unaffected by OS. No safety or effectiveness concerns .
Imaging Modalities	CT	MR and CT	CT	Same as the predicate device(s) with the exception that the primary predicate also allows MR inputs.
DICOM Compliant	Yes	Yes	Yes	Same as predicate device(s)
Import and display CT images	Yes	Yes	Yes	Same as predicate device(s)
Post process CCT images	Yes	Yes	Yes	Same as predicate device(s)
Images can be displayed by study and series	Yes	Yes	Yes	Same as predicate device(s)
2D Imaging	Yes	Yes	Yes	Same as predicate device(s)
2D Measurement	Yes	Yes	Yes	Same as predicate device(s)
3D Imaging	Yes	Yes	Yes	Same as predicate device(s)

Multiplanar reformatting (MPR)	Yes	Yes	Yes	Same as predicate device(s)
Segmentation of Region of Interest	Manual and Semi-Automatic (using Machine Learning technique) Segmentation of Coronary Vessels, Including Lumen and Vessel Wall Structures.	Manual and Semi-Automatic (using Machine Learning technique) Centerline Generation of the Coronary Vessels.	Manual and Semi-Automatic (using Machine Learning Technique) Segmentation of Coronary Vessels, Including Lumen and Vessel Wall Structures.	Same as the predicate device(s), with the exception that the primary predicate does not offer segmentation of the lumen and vessel wall structures. The successful passing of the V&V performance testing has demonstrated that the addition of semi-automatic segmentation of the lumen and vessel wall structures does not raise new questions of safety.
Plaque Thresholds	Yes	No	Yes	Both the subject device and secondary predicate device provide plaque thresholds.
Measurements				
Signal Density [HU]	Yes	Yes	Yes	Same as predicate device(s)
Distance Measurements (Vessel, Lesion, Length) [mm]	Yes	Yes	Yes	Same as predicate device(s)
Volumetric Plaque Measurements [mm^3]	- Non-Calcified Plaque (NCP) - Low-Attenuation Plaque (LAP) - Calcified Plaque (CP) - Total Plaque	- Calcified Plaque (CP)	- Total Vessel - Total Lumen - Non-Calcified Plaque (NCP) - Low-Density Non-Calcified Plaque (LD-NCP) - Calcified Plaque (CP) - Total Plaque	The subject device and the secondary predicate display the same measurements, with the exception of Total Vessel and Total Lumen – which are calculated but not reported as a device output.
Remodeling Index	Yes	No	Yes	Same as the secondary predicate device.
Stenosis [%]	- Diameter-Based Stenosis - Area-Based Stenosis	- Diameter-Based Stenosis - Area-Based Stenosis	- Diameter-Based Stenosis - Area-Based Stenosis	Same as predicate device(s)

VII. PERFORMANCE DATA AND TESTING

Performance testing was conducted to verify compliance with specified design requirements in accordance with ISO 13485:2016, IEC 62304:2015, ISO 14971:2019, and DICOM standards.

Verification and validation testing were conducted to ensure specifications and performance of the device and were performed per the FDA Guidance *"Technical Performance Assessment of Quantitative Imaging in Radiological Device Premarket Submission".* No clinical studies were necessary to support substantial equivalence.

The Coronary Plaque Module has been tested according to the specifications that are documented in a Master Software Test Plan. Testing is an integral part of Circle Cardiovascular Imaging Inc.'s software development as described in the company's product development process.

Cybersecurity Testing

The Coronary Plaque Module has been designed to meet cybersecurity requirements in accordance with FDA Guidance "*Cybersecurity in Medical Devices: Quality System Considerations and Content of Premarket Submissions"*, through the use of threat modeling, software composition analysis (SCA), static analysis, vulnerability testing, and a risk assessment based on exploitability and severity of harm.

Penetration testing was conducted to ensure that there were no unidentified vulnerabilities and that the appropriate risk control measures were implemented to protect from known vulnerabilities when the device subject to a source of threat.

Circle maintains a cybersecurity risk management plan for post-market monitoring and response.

Validation of non-Machine Learning Outputs

The validation of non-ML and mathematical outputs in the Coronary Plaque Module have been performed through general in-house software QA verification and validation processes including unit tests, content/phantom tests, quantitative and qualitative analysis, and visual/manual evaluation.

Validation of Machine Learning Derived Outputs

The Machine Learning (ML) algorithms of the Coronary Plaque Module have been trained and tested on images acquired from major vendors of CT imaging devices. All data used for validation were not used during the development of the ML algorithms. Image information for all samples was anonymized and limited to ePHI-free DICOM headers. The validation data was sourced from multiple sites, with 100% of the data sampled from US sources.

Coronary Plaque Module 510(k) Summary

The performance of the ML-based coronary vessel and lumen wall segmentation algorithm was evaluated against pre-defined acceptance criteria and compared to a reference standard established from three expert annotators. Segmentation accuracy was quantified using the Dice Similarity Coefficient (DSC) and Hausdorff Distance (HD), while the correlation of derived plaque volumes across plaque compositions was assessed with the Pearson Correlation Coefficient (PCC). All performance testing results met Circle's pre-defined acceptance criteria.

Endpoint	Results	Pass / Fail
Lumen Mean DSC	0.76	Pass
Wall Mean DSC	0.80	Pass
Lumen Mean HD	0.77 mm	Pass
Wall Mean HD	0.87 mm	Pass
TP PCC	0.97	Pass
CP PCC	0.99	Pass
NCP PCC	0.93	Pass
LAP PCC	0.74	Pass

The ML algorithms of the Coronary Plaque Module demonstrated consistent and comparable performance across diverse subgroups, including variations in scanner vendor, tube current, pixel resolution, slice thickness, patient age, sex, vessel location, and plaque lesion volume.

VIII. CONCLUSION

The information submitted in this premarket notification, including the performance testing and predicate device comparison, support the safety and effectiveness of the Coronary Plaque Module as compared to the predicate device(s) when used for the defined intended use.