July 29, 2026

Cleerly, Inc.
Felicia Hosey
Senior Director, Regulatory Affairs
1099 18th St., Suite 2860
Denver, CO 80202

Re: K261210
Trade/Device Name: Cleerly Plaque
Regulation Number: 21 CFR 892.2050
Regulation Name: Medical Image Management And Processing System
Regulatory Class: Class II
Product Code: QIH, LLZ
Dated: July 1, 2026
Received: July 2, 2026

Dear Felicia Hosey:

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.

FDA's substantial equivalence determination also included the review and clearance of your Predetermined Change Control Plan (PCCP). Under section 515C(b)(1) of the Act, a new premarket notification is not

required for a change to a device cleared under section 510(k) of the Act, if such change is consistent with an established PCCP granted pursuant to section 515C(b)(2) of the Act. Under 21 CFR 807.81(a)(3), a new premarket notification is required if there is a major change or modification in the intended use of a device, or if there is a change or modification in a device that could significantly affect the safety or effectiveness of the device, e.g., a significant change or modification in design, material, chemical composition, energy source, or manufacturing process. Accordingly, if deviations from the established PCCP result in a major change or modification in the intended use of the device, or result in a change or modification in the device that could significantly affect the safety or effectiveness of the device, then a new premarket notification would be required consistent with section 515C(b)(1) of the Act and 21 CFR 807.81(a)(3). Failure to submit such a premarket submission would constitute adulteration and misbranding under sections 501(f)(1)(B) and 502(o) of the Act, respectively.

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 Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (Preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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 Management System Regulation (QMSR) (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,

for

Jessica Lamb, Ph.D.
Assistant Director
Imaging Software Team
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

Indications for Use

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.	K261210

Please provide the device trade name(s).

Cleerly Plaque

Please provide your Indications for Use below.

Cleerly Plaque is a software module used in conjunction with Cleerly LABS, designed to assist in the evaluation of coronary artery disease (CAD) by identifying, characterizing, and quantifying coronary plaque in patients undergoing coronary computed tomography angiography (CCTA).

The software is not intended to replace the skill and judgment of a qualified medical practitioner and should only be used by medical professionals experienced in examining and evaluating cardiac CT images. 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 dataset. 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.

Please select the types of uses (select one or both, as applicable).

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

510(k) Summary

K261210

This 510(k) Summary is provided per the requirements of section 21 CFR 807.92 on April 13, 2026.

1. Submitter

Submitter	Cleerly, Inc.
Contact Person	Felicia Hosey, RAC Senior Director, Regulatory Affairs
Address	1099 18th St Suite 2860 Denver CO 80202
Phone	(540) 814-1677
Email	Felicia.Hosey@cleerlyhealth.com

2. Device Information

Device Trade Name	Cleerly Plaque
Software Version	1.0
Common Name	Automated radiological image processing software
Classification Name	Medical image management and processing system.
Product Classification	Class II, § 892.2050
Primary Product Code	QIH
Subsequent Product Code	LLZ

3. Predicate Device

Trade Name	Cleerly LABS (v2.0)
Common Name	Automated radiological image processing software
Classification Name	Medical image management and processing system.
Product Classification	Class II, § 892.2050
Primary Product Code	QIH
Subsequent Product Code	LLZ
Submission Number	K242338

4. Device Description

Cleerly Plaque is a cloud-based, software-only module designed for use by medical professionals with specialized training in coronary computed tomography angiography (CCTA) interpretation and in the

software's analysis functions. The device operates as an add-on to the Cleerly LABS platform and provides semi-automated plaque analysis to support clinical assessment of coronary artery disease.

The software performs automated detection, labeling, and quantification of atherosclerotic plaque in the coronary arteries using a combination of machine learning algorithms and rule-based image processing. Cleerly Plaque identifies the major coronary vessels and branch segments, segments vessel lumen and plaque, classifies plaque type, and calculates quantitative metrics including plaque volume, composition percentages, and vessel geometry. Results are delivered in a structured format to the LABS platform for interactive visualization and user review.

Qualified image analysts may interact with Cleerly Plaque outputs within LABS to review analysis results and make manual adjustments to vessel or plaque annotations. Adjustments can include refinement of vessel centerlines or plaque contours using the visualization and editing tools available in the LABS software.

Outputs generated by Cleerly Plaque are intended to support clinical assessment of coronary plaque and are not a final diagnostic report. Results should be interpreted in conjunction with other relevant clinical information, including independent review of the source images. Cleerly Plaque is not intended for use in patients with prior coronary artery bypass graft (CABG) surgery.

5. Intended Use / Indications for Use

Cleerly Plaque is a software module used in conjunction with Cleerly LABS, designed to assist in the evaluation of coronary artery disease (CAD) by identifying, characterizing, and quantifying coronary plaque in patients undergoing coronary computed tomography angiography (CCTA).

The software is not intended to replace the skill and judgment of a qualified medical practitioner and should only be used by medical professionals experienced in examining and evaluating cardiac CT images. 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 dataset. 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.

6. Substantial Equivalence

Cleerly Plaque has the same intended use and fundamental principles of operation as the legally marketed predicate device, Cleerly LABS v2.0 (K242338). Both devices assist trained medical professionals in the evaluation of coronary artery disease (CAD) by analyzing and quantifying coronary plaque from coronary computed tomography angiography (CCTA) scans. Differences in Indications for Use reflect the modular implementation of the subject device and do not alter the clinical intent, patient population, or conditions of use.

The subject device is implemented as a modular software component used in conjunction with the Cleerly LABS platform, whereas the predicate device incorporated plaque analysis within a single, integrated software system. The subject device also includes updated AI/ML architectures and workflow refinements. Despite these differences, both devices use the same fundamental technologies for coronary artery extraction, vessel labeling, lumen and plaque segmentation, and quantitative plaque analysis. These technological differences do not raise new questions of safety and effectiveness, as they do not change the types of outputs, clinical workflow, or user interpretation of results.

Non-clinical performance testing, including software verification and validation, as well as clinical performance evaluation, demonstrate that the subject device performs as intended and is as safe and effective as the predicate device.

The following table compares the key features of the subject and predicate devices.

Attribute	**Subject Device** **Cleerly Plaque**	**Predicate Device** **Cleerly LABS (v2.0), K242338**
Primary Product Code	QIH	-same-
Subsequent Product Code	LLZ	-same-
Indications for Use	Cleerly Plaque is a software module used in conjunction with Cleerly LABS, designed to assist in the evaluation of coronary artery disease (CAD) by identifying, characterizing, and quantifying coronary plaque in patients undergoing coronary computed tomography angiography (CCTA). The software is not intended to replace the skill and judgment of a qualified medical practitioner and should only be used by medical professionals experienced in examining and evaluating cardiac CT images. 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 dataset. 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.	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. 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.
Intended User	Trained medical professionals and Cleerly Services (Core Lab) analysts	-same-
Prescription Use	Yes	-same-

Attribute	Subject Device Cleerly Plaque	Predicate Device Cleerly LABS (v2.0), K242338
Image Source	CCTA	-same-
Data Input	DICOM 3.0 Compliant (or higher) + LABS Job information	DICOM 3.0 Compliant (or higher)
Output (final)	Visualization of the Cleerly plaque analysis in the LABS CORONARY Report	-same-
Plaque Workflow Integration	Modular software add-on	Monolithic within a single application (i.e., analysis + advanced plaque analysis)
Intended Function	Automated extraction, labeling, and segmentation of coronary anatomy and plaque.	-same-

7. Performance Data

Performance testing was conducted to verify compliance with specified design requirements in accordance with ISO 13485 and ANSI AAMI IEC 62304, ISO 14971. Verification and validation activities were performed across the full software lifecycle and no clinical studies were necessary to support substantial equivalence.

7.1 Software Testing

Cleerly Plaque underwent software verification and validation in accordance with ANSI/AAMI IEC 62304:2005/A1:2016 to ensure functionality, performance, and integration with the Cleerly LABS platform. Testing included module-level verification, integration testing within the LABS environment, and system-level validation of the end-to-end workflow. Results of testing confirmed that the software requirements met predefined acceptance criteria.

7.2 Cybersecurity

As Cleerly Plaque is deployed as an add-on module to the Cleerly LABS platform, cybersecurity controls for device and data protection are implemented and managed within the Cleerly LABS environment. The Cleerly LABS platform incorporates security features designed to protect data confidentiality, integrity, and availability. Cybersecurity risk management, including risk analysis and mitigation, was conducted in accordance with FDA guidance, *Cybersecurity in Medical Devices: Quality System Considerations and Content of Premarket Submissions*. Testing and controls implemented at the platform level ensure that the combined system remains safe and effective.

7.3 Performance Evaluation

Cleerly Plaque performance for coronary plaque quantification was evaluated using de-identified U.S. CCTA studies on the Cleerly LABS platform. The validation dataset included 120 studies representing a broad spectrum of coronary artery disease and multiple scanner manufacturers. A reference standard was established for each study by expert readers following a standardized annotation process. Outputs for plaque measurements were compared against this reference standard. Performance metrics included correlation of lumen, vessel and plaque volumes, as well as agreement for low-density plaque

measurements. All metrics met predefined acceptance criteria, demonstrating that Cleerly Plaque provides accurate and reliable plaque quantification across the intended use population.

Metric	Measure	Result [95% CI]	Pass/Fail
Overlap Ratio*	Ratio	96% [95%, 98%]	Pass
Lumen Volume	Correlation	0.983 [0.981, 0.985]	Pass
Vessel Volume	Correlation	0.985 [0.983, 0.986]	Pass
Total Plaque Volume	Correlation	0.973 [0.969, 0.976]	Pass
Total Calcified Plaque Volume	Correlation	0.946 [0.939, 0.952]	Pass
Total Non-Calcified Plaque Volume	Correlation	0.916 [0.905, 0.925]	Pass
Low-Density Non-Calcified Plaque Volume	Correlation	0.414 [0.32, 0.45]	Pass
Low-Density Non-Calcified Plaque Volume [< 2.3 mm3]	Agreement	97.8% [96.9%, 98.7%]	Pass
*Overlap ratio reflects comparison of corresponding main coronary vessels between Cleerly LABS and the reference dataset using identical image series to account for cardiac phase differences.			

7.4 Clinical Performance Evaluation

No clinical testing was conducted to demonstrate safety or effectiveness as the device's non-clinical testing was sufficient to support the intended use of the device.

8. Conclusions

Based on the information submitted in this premarket notification and conclusions drawn from the testing, Cleerly Plaque raises no new or different questions of safety and effectiveness and is substantially equivalent to the predicate device in terms of safety, efficacy and performance.

9. Predetermined Change Control Plan (PCCP)

The Cleerly Plaque PCCP outlines two planned modifications to improve coronary artery tree extraction, vessel labeling, and plaque quantification performance. These include (1) model re-training using an expanded, and more diverse dataset of CCTA scans to update internal model parameters, and (2) fine-tuning module-specific pre-processing and post-processing steps to optimize data preparation and deterministic transformations within predefined bounds. Each proposed change will be implemented according to a thorough modification protocol and must satisfy performance standards. This includes demonstrating non-inferiority to the original model; specifically, the modified modules must maintain an overlap ratio for vessel centerlines of ≥ 0.80 and demonstrate non-inferior performance for the Dice Similarity Coefficient for total plaque segmentation. Established performance assessment and validation protocols will be used, with modifications implemented offline through controlled retraining, verification, and validation processes prior to deployment to minimize risk. Pre-defined acceptance criteria must be fulfilled before any model update. All authorized modifications made under the PCCP will be documented and included in the device's labeling, where applicable, as the modifications are released. Controlled user notification is conducted via established communication procedures, including release notices and version documentation updates, in accordance with the PCCP.