July 29, 2026

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

Re: K260588
Trade/Device Name: Cleerly LABS
Regulation Number: 21 CFR 892.2050
Regulation Name: Medical Image Management And Processing System
Regulatory Class: Class II
Product Code: LLZ
Dated: July 1, 2026
Received: July 1, 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.

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.	K260588

Please provide the device trade name(s).

Cleerly LABS

Please provide your Indications for Use below.

Cleerly LABS is a web-based software application intended to be used by trained medical professionals as an interactive tool for processing, analyzing and viewing cardiac computed tomography (CT) data to assess coronary anatomy in patients who have undergone Coronary Computed Tomography Angiography (CCTA) for the evaluation of coronary artery disease (CAD) or suspected CAD.

This software post-processes CT images obtained from a CT scanner and 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 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 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.

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)
Please select the age group(s) for which the device(s) is to be used.	☐ Neonates/Newborns (Birth to < 29 days old) ☐ Infants (29 days old to < 2 years old) ☐ Children (2 years old to < 12 years old) ☐ Adolescents (12 years old to < 22 years old) ☒ Adults (22 years old and greater)

510(k) Summary

This 510(k) Summary is provided per the requirements of section 21 CFR 807.92 on July 14th, 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 LABS
Software Version	3.0
Common Name	Automated radiological image processing software
Classification Name	Medical image management and processing system.
Product Classification	Class II, § 892.2050
Primary Product Code	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 LABS is a cloud-based, software-only medical device platform that provides core capabilities for cardiovascular image analysis. It enables trained medical professionals to analyze 2D/3D coronary images

acquired from Coronary Computed Tomography Angiography (CCTA) scans and supports assessment of patients suspected of coronary artery disease (CAD).

The platform employs a hub-and-spoke, modular architecture that facilitates end-to-end study management, interactive review, and analysis, while supporting integration with separate software modules to extend functionality. The LABS platform itself does not perform AI/ML-based analysis, but displays outputs generated by connected modules.

Cleerly LABS uses rule-based post-processing calculations executed on secure cloud-based backend services to evaluate vessel lumens, vessel walls, plaque composition (quantified by Hounsfield Unit density), and stenosis at the lesion, segment, vessel, territory, and patient levels. 2D and 3D images are presented to the user for review and, where permitted, manual editing.

Cleerly LABS provides a visualization of the analysis results in the CORONARY Report, a structured and interactive report that details atherosclerosis and stenosis findings. Users can review vessel lumens, vessel walls, plaque characteristics based on Hounsfield Unit thresholds, and stenosis measurements. LABS may display or export additional information only when returned by a connected add-on module. Outputs from LABS may also be exported to a user's PACS system and are intended to support clinical decision-making. Outputs must be reviewed and interpreted by trained medical professionals in conjunction with other relevant clinical information.

The software does not perform any functions that could not be accomplished by a trained user with manual methods; its purpose is to save time and automate potentially error-prone tasks, while allowing results to be reviewed as part of the normal clinical workflow.

5. Indications for Use

Cleerly LABS is a web-based software application intended to be used by trained medical professionals as an interactive tool for processing, analyzing and viewing cardiac computed tomography (CT) data to assess coronary anatomy in patients who have undergone Coronary Computed Tomography Angiography (CCTA) for the evaluation of coronary artery disease (CAD) or suspected CAD.

This software post-processes CT images obtained from a CT scanner and 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 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 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.

6. Substantial Equivalence

Cleerly LABS has the same Intended Use and principles of operation as the legally marketed predicate device, Cleerly LABS (v2.0) (K242338). The Indications for Use are identical in purpose to the predicate, with only minor editorial clarifications.

The subject device employs a modular software architecture, whereas the predicate device utilized an integrated software structure. Despite this difference in software design, the subject and predicate devices use the same core technologies for image processing, quantitative analysis, visualization and reporting. The software design differences do not alter the underlying computational methods used to generate clinical information and do not impact device functionality or performance.

This technological difference does not raise different questions of safety and effectiveness, as supported by the reference device. Non-clinical performance testing, including software verification and validation, has demonstrated that Cleerly LABS 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 LABS	Predicate Device Cleerly LABS (v2.0), K242338
Primary Product Code	LLZ	QIH
Subsequent Product Code	n/a	LLZ
Indications for Use	Cleerly LABS is a web-based software application intended to be used by trained medical professionals as an interactive tool for processing, analyzing and viewing cardiac computed tomography (CT) data to assess coronary anatomy in patients who have undergone Coronary Computed Tomography Angiography (CCTA) for the evaluation of coronary artery disease (CAD) or suspected CAD. This software post-processes CT images obtained from a CT scanner and 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 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 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.	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

Attribute	Subject Device Cleerly LABS	Predicate Device Cleerly LABS (v2.0), K242338
		smaller than the scanning resolution may be present.
Operating Platform	Client-Server Google Chrome Application	-same-
Software Structure	Modular, hub and spoke	Monolithic with select add-on functionality
Workflow - Human-in-the-loop (HITL)	Yes	-same-
Workflow - Human-out-of-the-loop (HOOTL)	Yes	-same-
Image Input	DICOM 3.0 Compliant (or higher)	-same-
Image Acquisition	Coronary CT Images	-same-
Secured Network Server Integration	Yes	-same-
Study Analysis	Yes	-same-
Tools – Navigation	Yes	-same-
Study Analysis Tools – Editing/ Visualization	Yes	-same-
2D / 3D Imaging	Yes	-same-
Multiplanar Reformat (MPR)	Yes	-same-
Segmentation of Region of Interest	Yes	-same-
Plaque Composition Image Overlay	Yes	-same-
Hounsfield Unit (HU)	Yes	-same-
Distance Measurements	Yes	-same-
Volumetric Measurements	Yes	-same-
Remodeling Index	Yes	-same-
Stenosis	Yes	-same-
Advanced AI/ML Plaque Analysis	No [separate module]	Yes
Rule-based Calculations	Yes	-same-

7. Performance Data

Performance testing was conducted to verify compliance with specified design requirements in accordance with ISO 13485, ANSI AAMI IEC 62304, ISO 14971 and DICOM standards. 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

The Cleerly LABS software platform underwent comprehensive verification and validation in accordance with ANSI AAMI IEC 62304:2005/A1:2016, *Medical Device Software - Software Life Cycle Processes* [Including Amendment 1 (2016)] to ensure functionality, performance and compliance. Testing included

automated and manual testing, end-to-end integration testing of the complete system workflow and cybersecurity assessments to ensure vulnerabilities are identified and risks are mitigated, data is protected, and compliance is verified against industry standards. Results of testing confirmed that the software requirements fulfilled the pre-defined acceptance criteria.

7.2 Cybersecurity

Cleerly LABS has implemented security features for device and data protection. Cybersecurity testing included verification and validation of cybersecurity controls including manual and automated testing, vulnerability testing, and penetration testing. Cybersecurity requirements, risk analysis, and mitigation was addressed in accordance with FDA guidance, "*Cybersecurity in Medical Devices: Quality System Considerations and Content of Premarket Submissions*". Cleerly performs post-market monitoring to assess real and perceived cybersecurity vulnerabilities and uses specific software testing tools to ensure that the device remains safe and effective. Penetration testing was conducted to ensure that no unidentified vulnerabilities existed and that appropriate risk control measures were implemented to protect against known vulnerabilities when the device is subject to potential threats. Results of testing confirmed that the software requirements fulfilled the pre-defined acceptance criteria.

7.3 Performance Evaluation

Performance of Cleerly LABS for coronary anatomy and plaque quantification was evaluated using de-identified U.S. CCTA studies. Performance testing was conducted using the complete processing pipeline consisting of Cleerly Plaque (K261210) followed by Cleerly LABS, with rule-based post-processing calculations performed by Cleerly LABS using plaque analysis outputs generated by Cleerly Plaque. 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. Plaque analysis outputs generated by Cleerly Plaque and the resulting rule-based post-processing calculations performed by Cleerly LABS 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 the LABS processing pipeline provides accurate and reliable coronary and plaque quantification across the intended use population.

Metric	Measure	Result [95% CI]	Pass/Fail
Overlap Ratio*	Ratio	94.8% [92.5%, 97.1%]	Pass
Lumen Volume	Correlation	0.98 [0.982, 0.986]	Pass
Vessel Volume	Correlation	0.98 [0.982, 0.986]	Pass
Total Plaque Volume	Correlation	0.97 [0.965, 0.972]	Pass
Total Calcified Plaque Volume	Correlation	0.94 [0.936, 0.949]	Pass
Total Non-Calcified Plaque Volume	Correlation	0.90 [0.888, 0.909]	Pass
Low-Density Non-Calcified Plaque Volume	Correlation	0.57 [0.530, 0.606]	Pass
Low-Density Non-Calcified Plaque Volume [< 2.3 mm3]	Agreement	97.7% [96.8%, 98.5%]	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 LABS 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.