March 7, 2025

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

Re: K242338
Trade/Device Name: Cleerly LABS (v2.0)
Regulation Number: 21 CFR 892.2050
Regulation Name: Medical Image Management And Processing System
Regulatory Class: Class II
Product Code: QIH, LLZ
Dated: August 7, 2024
Received: February 10, 2025

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 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,

, 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

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.

Submission Number *(if known)*

K242338

Device Name

Cleerly LABS (v2.0)

Indications for Use *(Describe)*

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.

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.

K242338 510(k) Summary

This 510(k) Summary is provided per the requirements of section 21 CFR 807.92 on March 5th, 2025.

1. Submitter

Submitter	Cleerly, Inc.
Contact Person	Amit Relia, Vice President, Regulatory and Quality Affairs
Address	1099 18th St Suite 2860, Denver CO 80202
Phone	(949) 701-6918
Email	Amit.Relia@cleerlyhealth.com

2. Device Information

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

3. Predicate Device

Trade Name	Cleerly LABS (v2.0)
Common Name	System, Image Processing, Radiological
Classification Name	Medical image management and processing system.
Product Classification	Class II, § 892.2050
Product Code	LLZ
Submission Number	K202280

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 of having 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.
The user is then able to edit the suggested segmentation as well as adjust plaque thresholds, demarcate stenosis, stents, and chronic total occlusions (CTOs) as well as select dominance and indicate coronary anomalies. Plaque, stenosis, and vessel measurements are output based on the combination of user-editable segmentation and user-placed stenosis, stent, and CTO markers. These outputs are mathematical calculations and are not machine-learning based.

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 LABS software does not perform any functions that could not be accomplished by a trained user with manual tracing methods or other commercially available software. Rather, it represents a more robust semiautomatic software intended to enhance the performance of time-intensive, potentially error-prone, manual tasks, thereby improving efficiency for medical professionals in the assessment of coronary artery disease (CAD).

5. Intended Use / Indications for Use

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.

6. Substantial Equivalence

The subject version of Cleerly LABS has an identical intended use and similar operating principles and technological characteristics as the previously cleared predicate Cleerly LABS v2.0 (K202280) device. The subject device introduces modifications to the product labeling as well as changes to the device's operating principle (i.e., workflow) and minor incremental technological enhancements/changes. The modifications do not introduce any changes to the previously cleared existing algorithms or simple mathematical calculations (Cleerly LABS v2.0 (K202280)) and, consequently, could not significantly affect safety or effectiveness. Software testing demonstrates that the subject device Cleerly LABS continues to be safe and effective for its intended use and substantially equivalent to the predicate device Cleerly LABS v2.0.

In addition, the core functions of Cleerly LABS are supported by artificial intelligence, nonadaptive machine learning algorithms for CCTA processing and analysis. As a result, an administrative change to the product code has been introduced for the subject device.

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

Feature	Subject Device Cleerly LABS	Predicate Device Cleerly LABS v2.0, K202280
Primary Product Code	QIH	LLZ
Subsequent Product Code	LLZ	n/a
Operating Platform	Client-Server Google Chrome Application	Client-Server Google Chrome Application
Image Input	DICOM 3.0 Compliant (or higher)	DICOM 3.0 Compliant (or higher)
Image Acquisition	CT Images	CT Images
Secured Network Server Integration	Yes	Yes
Study Analysis Tools – Navigation	Yes	Yes
Study Analysis Tools – Editing/ Visualization	Yes	Yes
2D Imaging	Yes	Yes
3D Imaging	Yes	Yes
Multiplanar Reformat (MPR)	Yes	Yes
Segmentation of Region of Interest	Yes	Yes

Feature	Subject Device Cleerly LABS	Predicate Device Cleerly LABS v2.0, K202280
Plaque Composition Overlay	Yes	Yes
Hounsfield Unit (HU)	Yes	Yes
Distance Measurements	Yes	Yes
Volumetric Measurements	Yes	Yes
Remodeling Index	Yes	Yes
Stenosis	Yes	Yes
Coronary Anatomical Findings	Yes	Yes
Cleerly Core Lab Image Analysis	Yes	Not defined

7. Performance Data

Cleerly LABS has been designed, verified and validated in compliance with 21 CFR, Part 820.30 (Design Controls) requirements. The device has been designed to meet the requirements associated with ISO 14971, 2019-12, Medical Devices – Application of Risk Management to Medical Devices and AAMI TIR 57:2016, Principles for medical device security – Risk management. In addition, Cleerly complies with DICOM (Digital Imaging and Communications in Medicine) - Developed by the American College of Radiology and the National Electrical Manufacturers Association.

Software evaluation activities were performed in accordance with ANSI AAMI IEC 62304:2005/A1:2016, Medical Device Software - Software Life Cycle Processes [Including Amendment 1 (2016)] in multiple pre-production environments using simulated data and in production for release verification. Results of testing re-confirmed that the software requirements fulfilled the pre-defined acceptance criteria. Additionally, regression testing was completed, confirming that changes in technological characteristics did not affect the overall performance or functionality of the device.

Outputs of design control activities and software evaluation demonstrate that the modified device continues to be safe and effective for its intended use and is substantially equivalent and intended for the same clinical application, as the originally cleared device under K202280.

8. Clinical Data

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.

9. Conclusions

The subject version of Cleerly LABS has the same intended use, indications for use, software algorithm and fundamental technology design as the predicate Cleerly LABS v2.0 (K202280). The modifications to the product labeling as well as changes to the device's operating principle (i.e., workflow) and minor incremental technological enhancements/changes do not raise different questions of safety or efficacy. No changes have been made to machine learning algorithms or simple mathematical equations. Software testing demonstrates that the subject device Cleerly LABS continues to perform as intended; therefore, the subject version of Cleerly LABS is as safe and effective as the predicate Cleerly LABS v2.0 (K202280). Thus, Cleerly Labs v2.0 is substantially equivalent.