October 29, 2026

Cleerly, Inc.
Ivan Pulido
Senior Regulatory Affairs Specialist
1099 18th St., Suite 2860
Denver, Colorado 80202

Re: K262839
Trade/Device Name: Cleerly ISCHEMIA
Regulation Number: 21 CFR 870.2200
Regulation Name: Adjunctive Cardiovascular Status Indicator
Regulatory Class: Class II
Product Code: QXZ
Dated: September 29, 2026
Received: September 30, 2026

Dear Ivan Pulido:

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.

Before making any change significantly affecting the safety or effectiveness of the device, you must submit a new premarket notification in accordance with 21 CFR 807.81. 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

Office of Industry and Consumer Education (OICE) to ask a question about a specific regulatory topic. See the OICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-office-industry-and-consumer-education-oice) for more information or contact OICE by email (AskOICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

STEPHEN C. BROWNING -S

CDR Stephen Browning
Assistant Director
Division of Cardiac Electrophysiology,
Diagnostics, and Monitoring Devices
Office of Cardiovascular Devices
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.	K262839

Please provide the device trade name(s).

Cleerly ISCHEMIA

Please provide your Indications for Use below.

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.

Please select the types of uses.	☒ 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 08/10/2026.

1. Submitter

Submitter	Cleerly, Inc.
Contact Person	Ivan Pulido Senior Regulatory Affairs Specialist
Address	1099 18th St Suite 2860 Denver CO 80202
Phone	(512) 630-1709
Email	Ivan.pulido@cleerlyhealth.com

2. Device Information

Trade Name	Cleerly ISCHEMIA
Common Name	Adjunctive Epicardial Vascular Physiologic Status Indicator
Classification Name	Adjunctive cardiovascular status indicator
Product Classification	Class II, § 870.2200
Product Code	QXZ

3. Predicate Device

Trade Name	Cleerly ISCHEMIA
Common Name	Adjunctive Epicardial Vascular Physiologic Status Indicator
Classification Name	Adjunctive cardiovascular status indicator

Product Classification	Class II, § 870.2200
Product Code	QXZ

4. Device Description

Cleerly ISCHEMIAis an add-on software module to Cleerly LABS (K260588) 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.

5. 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.

6. Substantial Equivalence

The subject version of Cleerly ISCHEMIA has an identical intended use, the same analytical methodology, clinical functionality, operating principles, and fundamental technological characteristics as the previously cleared predicate Cleerly ISCHEMIA (K231335) device. This submission supports implementation of Cleerly ISCHEMIA with the modular software architecture described in Cleerly LABS (K260588). This submission also incorporates minor post-market software improvements and software maintenance updates necessary to support the current software environment. Software testing demonstrates that the subject device Cleerly ISCHEMIA continues to be safe and effective for its intended use and substantially equivalent to the predicate device.

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

Characteristic	Subject Device Cleerly ISCHEMIA, K262839	Predicate Device Cleerly ISCHEMIA, K231335
Regulation	21 CFR 870.2200	-same-
Generic Device Type	Adjunctive cardiovascular status indicator	-same-
SaMD	Yes	-same-
Intended Use	Providing adjunctive information a patient's cardiovascular condition (diagnostic aid for ischemia associated with coronary artery disease)	-same-
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 LABSsoftware. 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.	-same-
Anatomical Site	Cardiovascular	-same-
Users	Healthcare provider	-same-
Machine Learning-Based Algorithm	Yes	-same-
Operating Platform	Platform accessed via Client-Server Google Chrome Application	-same-
Risk Management	In accordance with ISO 14971:2019	-same-
Cybersecurity	Content of Premarket Submissions for Management of Cybersecurity in Medical Devices.	-same-
Usability	Usability assessment determined there were no critical tasks	-same-

Characteristic	Subject Device Cleerly ISCHEMIA	Predicate Device Cleerly ISCHEMIA, K231335
	associated with the use of the device.	
Pre-clinical Performance Testing	No animal studies were conducted.	-same-
Bench Performance Testing	Technical validation.	-same-
Clinical Performing Testing	Validated on a US/OUS cohort population, comprising 23 independent clinical sites representative of the intended use population.	-same-
Regulation	21 CFR 870.2200	-same-
Generic Device Type	Adjunctive cardiovascular status indicator	-same-
SaMD	Yes	-same-

7. Performance Data

Cleerly ISCHEMIA has been designed, verified and validated as described in ISO 13485, Clause 7.3 and its subclauses. The following non-clinical performance data were provided in support of substantial equivalence. The outputs of these design control and software evaluation activities demonstrate that the modified device remains safe and effective for its intended use. It is substantially equivalent to, and serves the identical clinical application as, the originally cleared device (K231335).

7.1. Risk Management

Assessment performed according to ISO 14971, *Medical Devices – Application of Risk Management to Medical Devices*. All hazards and failures for the subject device have the same severity and occurrence as the predicate. No new or unresolved unknown hazards, hazardous situations and harm were identified.

7.2. Software Testing

Software evaluation activities adhered to IEC 62304, *Medical Device Software - Software Life Cycle Processes*. Testing was conducted across multiple pre-production environments using simulated data, as well as in production for final release verification. These activities confirmed that all software requirements met their predefined acceptance criteria. Subsequent regression testing verified that technological updates did not compromise the device's overall performance or functionality.

8. Clinical Data

Clinical performance of the subject device was evaluated to confirm that the modifications did not impact its safety or effectiveness relative to the predicate device. The clinical study results from K231335 remain fully applicable to the subject device; therefore, no additional clinical studies were required to support substantial equivalence. The modifications introduced no clinically significant differences that would affect the device's safety or effectiveness..

9. Conclusions

The subject version of Cleerly ISCHEMIA has the same intended use, analytical methodology, clinical functionality, operating principles, and fundamental technological characteristics as the predicate Cleerly ISCHEMIA (K231335). The modifications to support implementation with the Cleerly LABS modular software architecture, together with minor software improvements and maintenance updates, do not raise different questions of safety or effectiveness, and no changes have been made to the Cleerly ISCHEMIA machine learning algorithms. Performance testing demonstrates that the subject device continues to perform as intended and is as safe and effective for its intended use as the predicate device. Thus, the results of performance testing support that the subject device is substantially equivalent to the predicate device for its intended use.