Cleerly Inc.
% John J. Smith, M.D., J.D.
Regulatory Counsel
Hogan Lovells US LLP
Columbia Square
555 Thirteenth Street, NW
WASHINGTON DC 20004

November 5, 2019

Re: K190868
Trade/Device Name: Cleerly Labs
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: Class II
Product Code: LLZ
Dated: October 9, 2019
Received: October 9, 2019

Dear Dr. Smith:

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 (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 located 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.

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 803) for devices or postmarketing safety reporting (21 CFR 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 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 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

Thalia T. Mills, Ph.D.
Director
Division of Radiological Health
OHT7: Office of In Vitro Diagnostics
and Radiological Health
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K190868

Device Name
Cleerly Labs

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 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.

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

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) Summary
Cleerly Labs (K190868)

1. General Information

Table 1: Cleerly, Inc. Information

510(k) Sponsor	Cleerly, Inc.
Address	101 Greenwich St, Suite 11C New York, NY 10006
Phone/Fax #	646-362-4255
Contact Person	Kimberly Elmore
Date Prepared	October 9, 2019

2. Device Information

Table 2: Cleerly Labs Information

Trade Name	Cleerly Labs (K190868)
Common Name	System, Image Processing, Radiological
Regulation Number	21 CFR 892.2050 *Picture Archiving And Communications System*
Classification	Class II
Product Code	LLZ
Predicate Device	Autoplaque (K122429)
Reference Device	SurePlaque (K043111)

3. 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 Computed Tomography (CT) angiographic scans. The software is a post-processing tool that aids in determining treatment paths for patients suspected to have coronary artery disease (CAD).

To aid in image analysis, tools are provided to users to navigate and manipulate images. Manual and semi-automatic segmentation of the coronary artery images are possible using editing tools, thus providing the user the flexibility to perform the coronary analysis.

The output of the software includes visual images of coronary arteries, distance and volume measurements of the lumen wall, vessel wall, and plaque, remodeling index as well as stenosis diameter and area. These measurements are based on user segmentation.

4. 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 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.

5. Software Functionality

Users of Cleerly Labs can edit the lumen and vessel walls of the suggested segmentation, and demarcate stenosis and stents, to more efficiently perform coronary analysis. Users are provided with image viewing tools to aid in their analysis. Plaque and stenosis measurements are output based on the combination of fully user-editable segmentation and user-placed demarcations of coronary artery characteristics.

6. Cybersecurity

Cleerly Labs has implemented security features for device and data protection. Cybersecurity requirements, risk analysis, and mitigation was addressed in accordance with FDA guidance, "Content of Premarket Submission for Management of Cybersecurity in Medical Devices".

7. Comparison of Technological Characteristics to the Predicate Devices

Table 3: Device Features Comparison Table

Feature	**Subject Device:** *Cleerly Labs (K190868)*	**Predicate Device:** *Autoplaque (K122429)*
Operating Requirements		
Platform	Client-Server Google Chrome Application	Windows OS
Image Input	DICOM 3.0 Compliant (or higher)	DICOM 3.0 Compliant (or higher)
Image Acquisition	CT Images	CT Images
Navigation Tools	• Window Width/Level • Zoom • Pan • Rotation • Tracker	• Window Width/Level • Zoom • Pan • Rotation • Tracker
Visualization / Edit Tools	• Lumen Wall • Vessel Wall • Segment • Stenosis • Centerline • Plaque • Chronic Total Occlusion (CTO) • Stent • Exclude • Distance	• Lumen Wall • Vessel Wall • Segment • Stenosis • Centerline • Plaque • Exclude • Distance
2D Imaging	Yes	Yes
3D Imaging	Yes	Yes
Multiplanar Reformat (MPR)	Yes	Yes
Segmentation of region of interest	Manual and Semi-Automatic	Manual and Semi-Automatic

Feature	Subject Device: *Cleerly Labs (K190868)*	Predicate Device: *Autoplaque (K122429)*
Plaque Composition Overlay	User-Modifiable Thresholds: • Non-Calcified Plaque (NCP) • Calcified Plaque (CP) • Low-Density Non-Calcified Plaque (LD-NCP)	User-Modifiable Thresholds: • Non-Calcified Plaque (NCP) • Calcified Plaque (CP) • Low-Density Non-Calcified Plaque (LD-NCP)
Quantification		
Hounsfield Unit (HU)	Yes	Yes
Distance Measurements	• Vessel • Lesion • Length	• Vessel • Lesion • Length
Volumetric Measurements	• Total Vessel • Total Lumen • Non-Calcified Plaque (NCP) • Low-Density Non-Calcified Plaque (LD-NCP) • Calcified Plaque (CP) • Total Plaque	• Total Vessel • Non-Calcified Plaque (NCP) • Low-Density Non-Calcified Plaque (LD-NCP) • Calcified Plaque (CP) • Total Plaque
Remodeling Index	Yes	Yes
Stenosis	• % Area Stenosis • % Diameter Stenosis	• % Area Stenosis • % Diameter Stenosis

8. Performance Data

Software verification and validation activities were performed in accordance with the standards identified in Table 4 below, in addition to the FDA Guidance documents, "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices" and "Content of Premarket Submission for Management of Cybersecurity in Medical Devices."

The software was considered as a “moderate” level of concern, since “a malfunction of, or a latent design flaw in, the Software Device could lead to an erroneous diagnosis or a delay in delivery of appropriate medical care that would likely lead to Minor Injury.”

During product development, potential hazards were controlled by a risk management plan including activities of risk analysis, risk mitigation, verification and risk-benefit analysis. Verification, validation and usability testing data demonstrated that the device meets all of its specification, including compliance with the following standards in **Table 4**.

Table 4: Standards applied to device development

Standards No	Standard Organization	Title	Version	Date
PS 3.1-3.20	NEMA	Digital Imaging And Communications In Medicine (DICOM) Set	2016	06-27-2016
62304	ANSI/AAMI/IEC	Medical device software - Software life cycle processes	2006+AMD1:2015 Edition 1.1	06-26-2016
14971	ISO	Medical Devices - Application Of Risk Management To Medical Devices	2007 Edition 2.0	03-01-2007
62366-1	ANSI AAMI IEC	Medical Devices - Part 1: Application Of Usability Engineering To Medical Device	2015 Edition 1.1	02-24-2015

Additionally, the performance of the software was compared to ground truth results produced by expert readers. Pearson Correlation Coefficients and Bland-Altman Agreements between Cleerly Labs and expert reader results is reported **Table 5**.

Table 5: Cleerly Labs Performance

Output	Pearson Correlation Coefficient	Bland-Altman Agreement
Lumen Volume	0.91	96%
Vessel Volume	0.93	97%
Total Plaque Volume	0.85	95%
Calcified Plaque Volume	0.94	95%
Non-Calcified Plaque Volume	0.74	95%
Low-Density-Non-Calcified Plaque Volume	0.53	97%

Non-Clinical Testing:

Safety, performance, cybersecurity and usability of Cleerly Labs have been evaluated and verified in accordance with software pre-defined specifications and applicable performance standards through software verification and validation testing.

- Verification and validation testing confirmed that the software requirements fulfilled the pre-defined acceptance criteria.
- A Usability test was conducted with U.S. board certified radiologists and technicians to ensure the clinical acceptability of the device.
- The machine learning algorithms were evaluated by comparing the output of the software to that of the ground truth using multiple ground truthers.
- A side-by-side comparison testing was conducted to evaluate the simple rule-based calculations as they compared to an already cleared device with a similar intended use.
- A cybersecurity 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 is subject to a source of threat.

The non-clinical verification and validation test results established that the device meets its design requirements and intended use. During the development, potential hazards were evaluated and controlled through risk management activities. The performance testing demonstrates that the device meets all its specifications.

Clinical Testing

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

9. Conclusion

Based on the information submitted in this premarket notification, and based on the indications for use, technological characteristics and performance testing comparison to the predicate, the Cleerly Labs device raises no new questions of safety or effectiveness and is substantially equivalent to the predicate in terms of safety, efficacy, and performance.