Canon Medical Informatics, Inc.
℅ Jay Vaishnav
Principal Regulatory Affairs Strategist
5850 Opus Parkway, Suite 300
MINNETONKA MN 55343

Re: K222662 October 14, 2022
Trade/Device Name: Vitrea CT Cardiac Analysis
Regulation Number: 21 CFR 892.2050
Regulation Name: Medical image management and processing system
Regulatory Class: Class II
Product Code: LLZ
Dated: August 31, 2022
Received: September 22, 2022

Dear Jay Vaishnav:

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,

Jessica Lamb, Ph.D.
Assistant Director
Imaging Software Team
DHT 8B: Division of Radiological Imaging
Devices and Electronic Products
OHT 8: 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: 06/30/2023
See PRA Statement below.

Submission Number *(if known)*

K222662

Device Name

Vitrea CT Cardiac Analysis

Indications for Use *(Describe)*

Vitrea® Coronary Artery Analysis (CT Cardiac Analysis) is intended for investigating coronary obstructive disease by providing a non-invasive survey of a patient's coronary arteries.

Clinicians can select any coronary artery to view the following anatomical references: the highlighted vessel in 3D, two rotatable curved MPR vessel views displayed at 90 degree angles to each other, and cross sections of the vessel. The clinician can semi automatically determine contrasted lumen boundaries, stenosis measurements, and maximum and minimum lumen diameters. In addition, clinicians can edit lumen boundaries and examine Hounsfield unit statistics.

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.

510(k) #: K222662

510(k) Summary

Prepared on: 2022-10-06

Contact Details

21 CFR 807.92(a)(1)

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Device Name

21 CFR 807.92(a)(2)

Device Trade Name	Vitrea CT Cardiac Analysis
Common Name	Medical image management and processing system
Classification Name	System, Image Processing, Radiological
Regulation Number	892.2050
Product Code	LLZ

Legally Marketed Predicate Devices

21 CFR 807.92(a)(3)

Predicate #	Predicate Trade Name (Primary Predicate is listed first)	Product Code
K052632	VITREA2 VERSION 3.8 MEDICAL IMAGE PROCESSING SOFT	LLZ

Device Description Summary

21 CFR 807.92(a)(4)

This submission is for the addition of a new feature, the Multi-Vessel preset, to the Vitrea CT Cardiac Analysis application. This application was originally cleared as "CT Coronary Analysis" in the predicate submission K052632 (Vitrea2 Version 3.8 Medical Image Processing Software). The application resides on the Vitrea AV platform, most recently cleared as K172855 (Vitrea Advanced Visualization, Version 7.6).

The submission is also intended to notify the Agency of the following non-significant changes to the software since the previous clearance, documented by Letters to File (LTF):

- Vessel Tracking for Low kV Scans
- Angiographic View

Canon Medical Informatics, Inc. maintains internal documentation of conformance with design controls for these changes.

DEVICE FUNCTIONS

This submission is for the addition of a new feature, the Multi-Vessel preset, to the Vitrea CT Cardiac Analysis application. The application was cleared as "CT Coronary Analysis" in K052632 (Vitrea2 v3.8 Medical Image Processing Software).

The previously cleared Vitrea CT Cardiac Analysis option (cleared in the predicate submission K052632 under the name "CT Coronary Analysis") provides a variety of tools and views for working with clinical CT images of the coronary arteries, heart, and surrounding tissue. The software supports CTA studies acquired by 4-slice and above multislice CT scanners, and includes the following features:

- Automatic segmentation of the heart from the rest of the anatomy
- Zero-click coronary vessel tree segmentation and automatic labeling of the three main coronary arteries
- Selection of any coronary artery for viewing with the Vessel Probe tool with easy centerline review and editing
- Full Vessel Probe capabilities for coronary arteries including the Lesion Tool, Vessel Walk, and Cath View
- A flythrough preset configured for flying through the coronary vessels (Global Illumination Rendering not available in the flythrough view)
- Unique Heart Mode to automatically orient oblique MPR views to show one short-axis view and two long-axis views
- Key findings classification during reading of the study for semi-automated structured report generation
- Measurement of plaque burden between the lumen and the outer wall with the SUREPlaque tool
- Display of a Transluminal Attenuation Gradient for probed vessels.

This submission adds the new Multi-Vessel preset feature. Whereas the predicate device offered initial automated probing and labeling of the three main coronary arteries, the new feature adds an additional initial automated probing (without labeling) of up to seventeen additional vessels in the vessel trees associated with the main coronary arteries: the left main/anterior tree, the left circumflex artery (LCX) tree, and the right coronary artery (RCA) tree. The tree structure allows edits to the trunk to be reflected on all the branch vessels. In both the subject and the predicate devices, the user has the ability to manually probe an unlimited number of additional vessels. The capability of either manually or automatically "probing" vessels was present in the predicate software.

SCIENTIFIC CONCEPTS THAT FORM THE BASIS FOR THE DEVICE

The scientific concept underlying the software is the image reconstruction method of curved multiplanar reformatting (MPR), commonly used for the visualization of complex three-dimensional structures, including vessels and treelike vessel structures.

SIGNIFICANT PHYSICAL AND PERFORMANCE CHARACTERISTICS OF THE DEVICE

Internal software verification and validation testing was completed on test cardiac CTA images to ensure that the Vitrea CT Cardiac Analysis software functions remained consistent with the software requirements, integration of the Multi-Vessel Probe feature into the software was successful, and the existing functionality of the Vitrea software platform was not degraded. The software achieved all product release criteria.

Intended Use/Indications for Use

21 CFR 807.92(a)(5)

Vitrea® Coronary Artery Analysis (CT Cardiac Analysis) is intended for investigating coronary obstructive disease by providing a non-invasive survey of a patient's coronary arteries.

Clinicians can select any coronary artery to view the following anatomical references: the highlighted vessel in 3D, two rotatable curved MPR vessel views displayed at 90 degree angles to each other, and cross sections of the vessel. The clinician can semi automatically determine contrasted lumen boundaries, stenosis measurements, and maximum and minimum lumen diameters. In addition, clinicians can edit lumen boundaries and examine Hounsfield unit statistics.

Indications for Use Comparison

21 CFR 807.92(a)(5)

The device has a different IFU statement from the predicate. There are two differences:

- The predicate device bundled multiple software applications, including Cardiac Functional Analysis, CT Colonography, VScore, and others. This submission is intended to modify only the Coronary Artery Analysis application. The remaining applications contained in the predicate software are not under review. The portions of the predicate IFU statement describing other applications have therefore been removed to reflect that only one application is under review. This change to the IFU is a purely administrative change that does not affect the device's technology or intended use or create a new intended use.

• In the predicate device, the relevant application was called "Coronary Artery Analysis." The subject device renames the application to "Vitrea CT Cardiac Analysis." This name change is intended to better describe the software function and more accurately specify that the software application is for analyzing cardiac CT images. The change does not affect the intended use of the software or create a new intended use.

Technological Comparison

21 CFR 807.92(a)(6)

The device has different technological characteristics from the predicate device.

This submission is for the addition of a new feature, the Multi-Vessel preset, to the Vitrea CT Cardiac Analysis software application (this application was cleared as part of the predicate device). After a cardiac CTA study was loaded into the software, the predicate device offered initial automatic probing and labeling of the three main coronary arteries. The new Multi-Vessel preset being added in the subject device expands the software's capability to include initial automatic probing (without labeling) of up to 17 additional vessels in the vessel trees associated with the main coronary arteries: the left main/anterior tree, the left circumflex artery (LCX) tree, and the right coronary artery (RCA) tree.

Once a vessel has been "probed" (whether manually by the user or automatically by the software after loading a study), the user can select the vessel, highlight it, view it in curved reformats or cross-sectional view, and view its centerline and contours. The ability to probe vessels either manually or automatically was present in the predicate device. The user has the ability to manually probe an unlimited number of additional vessels after initial automatic probing. The user has the ability to manually edit any automatic results.

Non-Clinical and/or Clinical Tests Summary & Conclusions

21 CFR 807.92(b)

Internal software verification and validation were completed to ensure that the CT Cardiac Analysis software functions remained consistent with the software requirements, the integration of the Multi-Vessel preset into the software was successful, and that the software did not degrade the existing functionality of the Vitrea AV software platform. The software achieved all product release criteria.

Validation was performed by producing, reviewing, and executing cardiac CTA test cases to ensure that features conformed to all new and previously defined specifications and to ensure that any risks were properly mitigated. The software traceability document provides the mapping between requirements, designs, risks, test cases, and final test run results.

The software was designed, developed, tested, verified, and validated according to written procedures. Testing confirmed that the software functions according to its requirements without impacting the existing functionality of either the CT Cardiac Analysis application or the Vitrea Advanced Visualization (AV) software platform.