April 10, 2025

Canon Medical Informatics, Inc.
% Jay Vaishnav
Director, Regulatory Affairs
5850 Opus Parkway, Suite 300
MINNETONKA, MN 55343

Re: K243240
Trade/Device Name: Vitrea CT VScore
Regulation Number: 21 CFR 892.1750
Regulation Name: Computed Tomography X-Ray System
Regulatory Class: Class II
Product Code: JAK
Dated: March 10, 2025
Received: March 11, 2025

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 (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,

Lu Jiang

Lu Jiang, Ph.D.
Assistant Director
Diagnostic X-Ray Systems Team
DHT8B: Division of Radiological Imaging
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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)*

K243240

Device Name

Vitrea CT VScore

Indications for Use *(Describe)*

The Vitrea CT VScore™ option is a calcium scoring application intended for the visualization, evaluation, and documentation of calcified lesions on non-contrast ECG-gated, cardiac CT DICOM images for patients aged 30 years or older. The application allows the user to segment and categorize the calcified lesions and calculate the calcium scores. The user can create a report including the data, images, literature, and additional relevant information. The application is intended to be used by qualified medical professionals to assist the physician in medical imaging assessment based on their professional judgment and other patient information. The calcification segmentation map is intended for informational use only.

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.

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510(k) #: K243240

510(k) Summary

Prepared on: 2025-03-11

Contact Details

21 CFR 807.92(a)(1)

Applicant Name	Canon Medical Informatics, Inc.
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Device Name

21 CFR 807.92(a)(2)

Device Trade Name	Vitrea CT VScore
Common Name	System, X-Ray, Tomography, Computed
Classification Name	Computed tomography x-ray system
Regulation Number	892.1750
Product Code(s)	JAK

Legally Marketed Predicate Devices

21 CFR 807.92(a)(3)

Predicate #	Predicate Trade Name (Primary Predicate is listed first)	Product Code
K003230	VSCORE WITH AUTO GATE MODEL	JAK

Device Description Summary

21 CFR 807.92(a)(4)

HOW THE DEVICE FUNCTIONS

The Vitrea CT VScore™ option is a calcium scoring application intended for the visualization, evaluation, and documentation of calcified lesions on cardiac CT images for patients aged 30 years or older.

The application allows the user to segment and categorize calcified lesions and calculate the calcium scores. The user can create a report including the data, images, literature, and additional relevant information. The application is intended to be used by qualified medical professionals to assist the physician in medical imaging assessment based on their professional judgment and other patient information.

The Vitrea CT VScore™ option is an interactive user-driven application. The application allows users to perform visualization, quantification and documentation of calcium lesions on cardiac CT studies.

The application provides a user interface with the following main functions:

-Allows manual selection of calcified lesions that meet selection criteria such a 3-pixel threshold and a 130 HU density threshold.
-Allows users to manually assign the selected calcium to the appropriate coronary and non-coronary categories.
-For selected calcium, calculates Agatston and volume scores.
-Allows users to select well-established, standard population databases and risk categories, along with literature references, to include in reports.
-Allows users to output documentation using standard DICOM objects (such as DICOM structured reporting objects).

SCIENTIFIC CONCEPTS THAT FORM THE BASIS OF THE DEVICE/PRINCIPLE OF OPERATION FOR ACHIEVING INTENDED EFFECT

The application takes standard DICOM images generated by CT scanners as input and provides a user interface permitting users to create the desired outputs as part of their clinical workflow. The device returns Agatston and volume calcium scores; well-established methods of calculation exist for these scores. Optionally, and for reporting purposes, the device displays patient scores in the context of well-established population reference databases and calcium scoring reporting systems.

PROPOSED CONDITIONS FOR USE

The application is intended to operate on cardiac CT images. The device is indicated for patients aged 30 or above.

PHYSICAL AND PERFORMANCE CHARACTERISTICS OF THE DEVICE

The device is Software as a Medical Device (SaMD) and has no hardware or material components.

HOW THE DEVICE INTERACTS WITH OTHER DEVICES AND THE PATIENT

The device is a software application that runs on the Vitrea Advanced Visualization platform. The device operates on cardiac CT DICOM images of a patient after they have been acquired. The device produces DICOM output, including DICOM SR objects.

The Vitrea CT VScore™ option is a calcium scoring application intended for the visualization, evaluation, and documentation of calcified lesions on non-contrast ECG-gated, cardiac CT DICOM images for patients aged 30 years or older. The application allows the user to segment and categorize the calcified lesions and calculate the calcium scores. The user can create a report including the data, images, literature, and additional relevant information. The application is intended to be used by qualified medical professionals to assist the physician in medical imaging assessment based on their professional judgment and other patient information. The calcification segmentation map is intended for informational use only.

Indications for Use Comparison 21 CFR 807.92(a)(5)

The IFU has been updated for clarity to better scope and clearly convey device use, and to align with current FDA regulations and practices surrounding similar devices. The changes are for clarification only and do not create a new intended use of the device.

Technological Comparison 21 CFR 807.92(a)(6)

The device has similar technological characteristics as the predicate device. The major differences in technological characteristics follow:

(1) The subject device offers updated cybersecurity controls and documentation intended to comply with the current FDA software guidance "Cybersecurity in Medical Devices: Quality System Considerations and Content of Premarket Submissions Guidance for Industry and Food and Drug Administration Staff Document," dated September 27, 2023.

(2) The subject device adds DICOM structured reporting objects.

Non-Clinical and/or Clinical Tests Summary & Conclusions 21 CFR 807.92(b)

Cybersecurity testing demonstrated that the device had a robust security posture. The cybersecurity of the device is greater than that of the predicate.

DICOM SR testing verified that DICOM SR files correctly represented clinical information, met DICOM standards, and were inter-operable with other systems. This verification demonstrates that the DICOM SR feature does not negatively impact the device's safety, effectiveness, or performance.

Canon believes that the conclusions drawn from the nonclinical testing demonstrate substantial equivalence.