November 28, 2025

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

Re: K252217
Trade/Device Name: CT VScore+
Regulation Number: 21 CFR 892.1750
Regulation Name: Computed Tomography X-Ray System
Regulatory Class: Class II
Product Code: JAK
Dated: October 17, 2025
Received: October 27, 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.
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DHT8B: Division of Radiologic 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.

510(k) Number *(if known)*
K252217

Device Name
CT VScore+

Indications for Use *(Describe)*
CT VScore+ is a software application intended for non-invasive evaluation of calcified lesions of the coronary arteries based on ECG-gated, non-contrast cardiac CT images for patients aged 30 years or older. The device automatically generates calcium scores for the coronary arteries (combined LM+LAD, RCA, LCX) and highlights the segmented calcium on the original CT image. The device also offers the option for the user to display the calcium scores in the context of reference data from the MESA and Hoff-Kondos databases.

The segmented arteries include combined LM+LAD, RCA, and LCX. To obtain separate LM and LAD results, the user must perform manual segmentation. The segmentation map of calcifications is intended for informational use only and is not intended for detection or diagnostic purposes. The 3D Calcium View output is provided strictly as an informational and supplementary output and should never be used alone as the method of reviewing the calcium segmentation.

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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CT VScore+ 510(k) Summary

510(k) #: K252217 Prepared on: 2025-11-21

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	**CT VScore+**
Classification Name	Computed tomography x-ray system
Common Name	System, X-Ray, Tomography, Computed
Regulation Number	21 CFR 892.1750
Product Code(s)	JAK

Legally Marketed Predicate Device 21 CFR 807.92(a)(3)

Predicate #	Predicate Trade Name	Product Code
K213725	GE CardIQ Suite	JAK

Device Description Summary 21 CFR 807.92(a)(4)

How the Device Functions

CT VScore+ is a software application intended for non-invasive evaluation of calcified lesions of the coronary arteries based on ECG-gated, non-contrast cardiac CT images for patients aged 30 years or older. The application runs on the Vitrea platform.

The device automatically generates Agatston and volume calcium scores for each of the coronary arteries (combined LM+LAD, RCA, LCX) based on the volume and density of the calcium deposits and highlights the Segmented calcium on the original CT image. The device also offers the option for the user to display the calcium scores in the context of reference data from the MESA and Hoff-Kondos databases.

The software uses deep learning-based segmentation methods. Users can edit the automated segmentation, including manually assigning calcifications to anatomical structures.

The device automatically outputs a combined LM+LAD score as the final automated output. To obtain separate LM and LAD results, the user must perform manual segmentation using the provided editing tools.

Scientific Concepts That Form The Basis Of The Device/Principle Of Operation For Achieving Intended Effect

The device reads DICOM images that meet input criteria. Using automatic processing, the device returns calcium segmentation and Agatston and volume scores for coronary arteries only. Optionally, and for reporting purposes, the device displays patient scores in the context of well-established population reference databases and calcium scoring reporting systems. Users can edit any automated outputs.

Proposed Conditions for Use

The application is intended to operate on ECG-gated, non-contrast cardiac CT images. The device is indicated for patients aged 30 or older.

Physical and Performance Characteristics of the Device

The device is Software as a Medical Device (SaMD) that operates on ECG-gated, non-contrast cardiac CT DICOM images.

Device development used a total of 210 unique patient datasets adhering to the inclusion/exclusion criteria, gathered from four institutions (two US sites and two Japanese sites).

Device performance was validated on 236 cases, in a study by three US board-certified physicians. In addition to this testing, software verification and validation activities were completed to ensure that the software functions remained consistent with the software requirements. The software achieved all product release criteria.

The developmental and validation data are independent at both the patient level and the site level.

How the Device Interacts With Other Devices and the Patient

The device does not interact directly with the patient. The device is a software application that runs on the Vitrea platform and processes ECG-gated non-contrast cardiac CT DICOM images. The device automatically generates Agatston and volume calcium scores for each of the coronary arteries (LAD+LM, RCA, LCX) based on the volume and density of the calcium deposits and highlights the segmented calcium on the original CT image. Results can be exported to image management, archival, or reporting systems that support DICOM standards for further review and interpretation.

Results can also be saved in DICOM Structured Reports (DICOM SR) format.

Intended Use/Indications for Use 21 CFR 807.92(a)(5)

CT VScore+ is a software application intended for non-invasive evaluation of calcified lesions of the coronary arteries based on ECG-gated, non-contrast cardiac CT images for patients aged 30 years or older. The device automatically generates calcium scores for the coronary arteries (combined LM+LAD, RCA, LCX) and highlights the segmented calcium on the original CT image. The device also offers the option for the user to display the calcium scores in the context of reference data from the MESA and Hoff-Kondos databases.

The segmented arteries include combined LM+LAD, RCA, and LCX. To obtain separate LM and LAD results, the user must perform manual segmentation. The segmentation map of calcifications is intended for informational use only and is not intended for detection or diagnostic purposes. The 3D Calcium View output is provided strictly as an informational and supplementary output and should never be used alone as the method of reviewing the calcium segmentation.

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

The subject device has a more restrictive IFU and includes a subset of the predicate functionality, non-invasive evaluation of calcified lesions of the coronary arteries based on ECG-gated, non-contrast cardiac CT images for patients aged 30 years or older. The predicate device also performs other functions, including analysis of CCTA images. This change in the IFU does not create a new intended use.

Technological Comparison 21 CFR 807.92(a)(6)

CT VScore+ incorporates a machine learning algorithm (deep learning-based segmentation) for coronary calcification identification and quantification. The device uses a proprietary Attention UNet architecture for segmentation, trained on a diverse dataset of ECG-gated, non-contrast cardiac CT scans. The device outputs Agatston and volume scores for combined LM+LAD, LCX, and RCA, and also provides a 3D calcium view for informational, supplementary visualization.

The table below summarizes the key feature/technological differences and similarities between the predicate device and the proposed device:

Characteristic	Subject Device (CT VScore+)	Predicate Device (CardIQ Suite K213725)	Analysis
Indications for Use	CT VScore+ is a software application intended for non-invasive evaluation of calcified lesions of the coronary arteries based on ECG-gated, non-contrast cardiac CT images for patients aged 30 years or older. The device automatically generates calcium scores for the coronary arteries (combined LM+LAD, RCA, LCX) and highlights the segmented calcium on the original CT image. The device also offers the option for the user to display the calcium scores in the context of reference data from the MESA and Hoff-Kondos databases. The segmented arteries include combined LM+LAD, RCA, and LCX. To obtain separate LM and LAD results, the user must perform manual segmentation. The segmentation map of calcifications is intended for informational use only and is not intended for detection or diagnostic purposes. The 3D Calcium View output is provided strictly as an informational and supplementary output and should never be used alone as the method of reviewing the calcium segmentation.	CardIQ Suite is a non-invasive software application designed to provide an optimized application to analyze cardiovascular anatomy and pathology based on 2D or 3D CT cardiac non contrast and angiography DICOM data from acquisitions of the heart. It provides capabilities for the visualization and measurement of vessels and visualization of chamber mobility. CardIQ Suite also aids in diagnosis and determination of treatment paths for cardiovascular diseases to include, coronary artery disease, functional parameters of the heart, heart structures and follow-up for stent placement, bypasses and plaque imaging. CardIQ Suite provides calcium scoring, a non-invasive software application, that can be used with non-contrasted cardiac images to evaluate calcified plaques in the coronary arteries, heart valves and great vessels such as the aorta. Calcium Scoring may be used to monitor the progression/regression of calcium in coronary arteries overtime, which may aid in the prognosis of cardiac disease.	The subject device has a more restrictive IFU and includes a subset of the predicate functionality, non-invasive evaluation of calcified lesions of the coronary arteries based on ECG-gated, non-contrast cardiac CT images for patients aged 30 years or older. The predicate device also performs other functions, including analysis of CCTA images. This change in the IFU does not create a new intended use.

Intended Use	The device is intended for use in adults aged 30 years and older. It automatically generates calcium scores for the coronary arteries and highlights the segmented calcifications on the original CT images. The intended use is to quantify coronary artery calcium from ECG-gated, non-contrast cardiac CT images to support clinical interpretation of cardiovascular risk.	CardIQ Suite is a collection of non-invasive software features intended to analyze CT cardiovascular anatomy and pathology and aid in determining treatment paths.	Subject device has a more restrictive IFU, subset of predicate functionality. No new intended use.
Device Input	Non-contrast, ECG-gated cardiac CT scans	Non-contrast, ECG gated cardiac CT scans or coronary CT angiography images (CCTA)	The subject device processes noncontrast cardiac CT coronary artery calcium (CAC) scans only, and does not operate on CCTA images. CAC and CCTA scans serve different clinical functions. This does not impact the safety or effectiveness of the subject device compared to the predicate.
Device Output	DICOM images with calcium highlighted. Total calcium scores as well as per-vessel scores for the LM+LAD, LCX, and RCA	Same	Same
Identification of calcium	Yes	Same	Same.
Comparison of calcium scores to cited literature	Yes	Yes	Similar. Both devices offer the option for the user to display the calcium scores in the context of data from well-established reference population databases (MESA; Hoff-Kondos).
Associates calcium with artery	Yes	Same	Similar. Both devices use deep learning methods to segment the coronary artery regions.
Methods	Deep learning methods used to segment coronary regions and assign calcium	Same	Exact predicate methods are unknown but likely similar.

Automation	Semi-automatic; Software initializes coronary calcium results.	Same	Same
Interactive definition of ROIs and assignment of calcium	Users can manually edit results, including manually assigning calcifications to anatomical structures	Same	Same. Both devices allow users to manually edit calcifications and assign them to labeled anatomical structures
Export as DICOM SR	Yes	Same	Same
3D Calcium View	A 3D rendered image, showing an optional supplemental view of segmented calcium in relation to full anatomy.	Not specified	Subject device output is supplementary only and should not be used for primary review.

In summary, the subject and predicate devices use different proprietary deep learning algorithms for coronary region segmentation. These differences do not raise new questions of safety or effectiveness. The subject device's algorithms have been validated through performance testing, meeting pre-specified acceptance criteria and demonstrating accuracy and reliability.

Non-Clinical and/or Clinical Tests Summary & Conclusions

CT VScore+ is an automatic coronary artery calcium (CAC) scoring software that incorporates a machine learning algorithm for coronary calcification segmentation. Performance testing was conducted to validate analytical accuracy and demonstrate substantial equivalence to the predicate device. Testing included retrospective clinical datasets and followed FDA-recognized statistical methods.

Truthing

The reference standard ground truth was established by consensus manual scoring on an FDA-cleared device (Vitrea CT VScore, K243240) and a 2+1 consensus process by three U.S. board-certified radiologists/cardiologists.

Dataset Independence

The CT VScore+ deep learning model was developed and validated using separate, diverse datasets to ensure robust and unbiased performance. The following is information about the development and validation datasets:

- **Development dataset**: 210 cases (94 training, 40 validation, 76 internal testing).
- **Pivotal validation dataset**: 236 independent cases, sourced from diverse U.S. sites and scanner vendors.

There was no overlap in sites or cases between the development and pivotal validation datasets.

Classification Performance-Based Summary

The following metrics were used to assess the device's overall performance:

- **Total Agatston Score ICC(2,1):** 0.997 [95% CI: 0.996–0.998] (Acceptance: >0.95)

- **Total Volume Score ICC(2,1):** 0.996 [95% CI: 0.995–0.997] (Acceptance: >0.95)
- **Per-Vessel ICCs:** LCx: 0.937; RCA: 0.990; LM+LAD: 0.983 (Acceptance: >0.90)
- **CAC-DRS 4-Class Kappa:** 0.959 [95% CI: 0.936–0.982] (Acceptance: >0.90)
- **CAC Standard 5-Class Kappa:** 0.958 [95% CI: 0.938–0.978] (Acceptance: >0.90)
- **Voxelwise Dice Score:** 0.920 overall; per-vessel DS: LCx 0.874, RCA 0.883, LM+LAD 0.958 (Informational metric)

In addition, Bland-altman analysis was conducted to demonstrate the agreement between the device's outputs and ground truth. The device met all predefined acceptance criteria, confirming strong agreement with ground truth. Subgroup performance results follow:

Technical Characteristics

- **Scanner Vendors:** Canon, GE, Siemens, Philips – ICC consistently >0.98 across all.
- **Slice Thickness:** 2.5 mm vs. 3.0 mm – ICC consistently >0.99 across all.
- **Reconstruction Kernel (FBP)** – ICC consistently >0.99 across all.
- **Noise Levels:** ICC consistently >0.98 across noise levels.

Patient Demographics

- **Patient Demographics:** ICC>0.98 for all sex and age groups.
- **Geographic Diversity:** Data from six U.S. states across four U.S. regions and multiple institution types. ICC>0.98 for all.

Disease Status

- **Valve calcification severity:** The device showed uniformly high agreement across “none,” “moderate,” and allowed “severe” categories (ICC ≈0.993–0.999), indicating that the presence of incidental valve calcification did not affect coronary calcium scoring performance. Severe mitral valve calcification cases were excluded.

- **CAC Burden:** Overall, subgroup testing confirmed robust performance across patient demographics, disease severity levels, and incidental cardiac findings. Detailed results are below:
  - **Very high calcium ranges (CAC-DRS 3, ≥300 AU; CAC-5-STD-4, >400 AU):** ICC values were extremely high (>0.99), confirming strong stability in higher-burden cases.
  - **Moderate calcium ranges (CAC-DRS 1&2, 1-299 AU; CAC-5-STD-2&3, 11–400 AU):** Agreement remained high (ICC ≈ 0.86–0.97), meeting expected acceptance levels for these clinically variable categories.
  - **Low calcium ranges (CAC-5-STD-1, 1–10 AU) and Zero calcium (CAC-DRS-0 and CAC-5-STD-0, 0 AU):** ICC is not applicable. These cases were handled per categorical scoring analysis: Among the fifty cases with confirmed zero calcium scores, nine (18%) were assigned nonzero scores by the software. No confirmed nonzero scores were assigned CAC=0.

Users should note the possibility that CAC=0 cases may be misclassified as having low nonzero CAC. All results should be reviewed by a physician, particularly in score ranges of 0-10 AU.

Conclusion

CT VScore+ demonstrated high analytical validity with ICC >0.99 for total scores, Kappa >0.95 for risk classification, and robust segmentation accuracy (Dice score ≥0.87 per vessel). Performance was consistent across subgroups, supporting generalizability. All acceptance criteria were met, and no new safety or effectiveness concerns were identified. The test results support the conclusion that CT VScore+ is as safe and as effective as the predicate device cleared under K213725.