TeraRecon, Inc.
Alexis Ferrier
Official Correspondent
4309 Emperor Boulevard
Suite 310
Durham, North Carolina 27703

Re: K250288
Trade/Device Name: TeraRecon Cardiovascular.Calcification.CT
Regulation Number: 21 CFR 892.2050
Regulation Name: Medical Image Management And Processing System
Regulatory Class: Class II
Product Code: QIH
Dated: January 31, 2025
Received: September 25, 2025

Dear Alexis Ferrier:

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,

Jessica Lamb
Assistant Director
DHT8B: Division of Radiologic Imaging
Devices and Electronic Products
OHT8: 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: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K250288

Device Name

TeraRecon Cardiovascular.Calcification.CT

Indications for Use *(Describe)*

TeraRecon Cardiovascular.Calcification.CT is intended to provide an automatic 3D segmentation of calcified plaques within the coronary arteries and outputs a mask for calcium scoring systems to use for calculations. The results of TeraRecon Cardiovascular.Calcification.CT are intended to be used in conjunction with other patient information by trained professionals who are responsible for making any patient management decision per the standard of care. TeraRecon Cardiovascular.Calcification.CT is a software as a medical device (SaMD) deployed as a containerized application. The device inputs are CT heart without contrast DICOM images. The device outputs are DICOM result files which may be viewed utilizing DICOM-compliant systems. The device does not alter the original input data and does not provide a diagnosis.
TeraRecon Cardiovascular.Calcification.CT is indicated to generate results from Calcium Score CT scans taken of adult patients, 30 years and older, except patients with pre-existing cardiac devices, electrodes, previous and established ischemic diseases (IMA, bypass grafts, stents, PTCA) and Thoracic metallic devices. The device is not specific to any gender, ethnic group, or clinical condition. The device's use should be limited to CT scans acquired on General Electric (GE) or Siemens Healthcare or their subsidiaries (e.g. GE Healthcare) equipment. Use of the device with CT scans from other manufacturers is not recommended.

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) #: K250288

510(k) Summary

Prepared on: 2025-10-23

Contact Details

21 CFR 807.92(a)(1)

Applicant Name	TeraRecon, Inc.
Applicant Address	4309 Emperor Boulevard Suite 310 Durham NC 27703 United States
Applicant Contact Telephone	6169806373
Applicant Contact	Ms. Alexis Ferrier
Applicant Contact Email	aferrier@concertai.com

Device Name

21 CFR 807.92(a)(2)

Device Trade Name	TeraRecon Cardiovascular.Calcification.CT
Common Name	Medical image management and processing system
Classification Name	Automated Radiological Image Processing Software
Regulation Number	892.2050
Product Code(s)	QIH

Legally Marketed Predicate Devices

21 CFR 807.92(a)(3)

Predicate #	Predicate Trade Name (Primary Predicate is listed first)	Product Code
K233211	AVIEW CAC	QIH

Device Description Summary

21 CFR 807.92(a)(4)

The TeraRecon Cardiovascular.Calcification.CT algorithm is an image processing software device that can be deployed as a containerized application (e.g., Docker container) that runs on off-the-shelf hardware or on a cloud platform. The device provides an automatic 3D segmentation of the coronary calcifications.

When TeraRecon Cardiovascular.Calcification.CT results are used in external viewer devices such as TeraRecon's Intuition or Eureka Clinical AI medical devices, all the standard features offered by the external viewer are employed.

The TeraRecon Cardiovascular.Calcification.CT algorithm is not intended to replace the skill and judgment of a qualified medical practitioner and should only be used by individuals that have been trained in the software's function, capabilities, and limitations.

Intended Use/Indications for Use

21 CFR 807.92(a)(5)

TeraRecon Cardiovascular.Calcification.CT is intended to provide an automatic 3D segmentation of calcified plaques within the coronary arteries and outputs a mask for calcium scoring systems to use for calculations. The results of TeraRecon Cardiovascular.Calcification.CT are intended to be used in conjunction with other patient information by trained professionals who are responsible for making any patient management decision per the standard of care. TeraRecon Cardiovascular.Calcification.CT is a software as a medical device (SaMD) deployed as a containerized application. The device inputs are CT heart without contrast DICOM images. The device outputs are DICOM result files which may be viewed utilizing DICOM-compliant systems. The device does not alter the original input data and does not provide a diagnosis.
TeraRecon Cardiovascular.Calcification.CT is indicated to generate results from Calcium Score CT scans taken of adult patients, 30 years and older, except patients with pre-existing cardiac devices, electrodes, previous and established ischemic diseases (IMA, bypass grafts, stents, PTCA) and Thoracic metallic devices. The device is not specific to any gender, ethnic group, or clinical condition. The device's use

should be limited to CT scans acquired on General Electric (GE) or Siemens Healthcare or their subsidiaries (e.g. GE Healthcare) equipment. Use of the device with CT scans from other manufacturers is not recommended.

Indications for Use Comparison

21 CFR 807.92(a)(5)

Indications for use (Subject Device) - TeraRecon Cardiovascular.Calcification.CT is intended to provide an automatic 3D segmentation of calcified plaques within the coronary arteries and outputs a mask for calcium scoring systems to use for calculations. The results of TeraRecon Cardiovascular.Calcification.CT are intended to be used in conjunction with other patient information by trained professionals who are responsible for making any patient management decision per the standard of care. TeraRecon Cardiovascular.Calcification.CT is a software as a medical device (SaMD) deployed as a containerized application. The device inputs are CT heart without contrast DICOM images. The device outputs are DICOM result files which may be viewed utilizing DICOM-compliant systems. The device does not alter the original input data and does not provide a diagnosis.
TeraRecon Cardiovascular.Calcification.CT is indicated to generate results from Calcium Score CT scans taken of adult patients, 30 years and older, except patients with pre-existing cardiac devices, electrodes, previous and established ischemic diseases (IMA, bypass grafts, stents, PTCA) and Thoracic metallic devices. The device is not specific to any gender, ethnic group, or clinical condition. The device's use should be limited to CT scans acquired on General Electric (GE) or Siemens Healthcare or their subsidiaries (e.g. GE Healthcare) equipment. Use of the device with CT scans from other manufacturers is not recommended.

Indications for Use (Predicate Device) - AVIEW CAC (233211)
A VIEW CAC provides quantitative analysis of calcified plaques in the coronary arteries using non-contrast/non-gated Chest er scans. It enables the calculation of the Agatston score for coronary artery calcification, segmenting and evaluating the right coronary artery and left coronary artery. Also provide risk stratification based on calcium score, gender, and age, offering percentile-based risk categories by established guidelines. Designed for healthcare professionals, including radiologists and cardiologists, A VIEW CAC supports storing, transferring, inquiring, and displaying CT data sets on-premises, facilitating access through mobile devices and Chrome browsers. A VIEW CAC analyzes existing noncontrast/non-gated Chest CT studies that include the heart of adult patients above the age of 40. Also, the device's use should be limited to er scans acquired on General Electric (GE) or its subsidiaries (e.g., GE Healthcare) equipment. Use of the device with CT scans from other manufacturers has not been validated or recommended.

Comparison of the Indications for Use:
There are several differences between the subject and predicate device indications for use. The subject device does not include functionality to provide professionals with tools to read, interpret, report or treatment plan. The subject device does not segment the right or left coronary arteries but rather the calcified plaques within the arteries. The subject device outputs a mask for calcium scoring systems to utilize while the predicate device outputs the calcium score. The predicate device provides risk stratification not included in the subject device. The subject device is intended to be utilized for adult patients (30 or older), while the predicate device is only on patients above the age of 40. The subject device allows for the user of gated CT images, while the predicate device allows for the input of non-gated chest CT images.

The differences in the two indications for use statement do not raise different safety and effectiveness questions because the differences are summarized as additional functionality that is offered by the predicate device in comparison to the subject device. The similarities in the two indications for use statements show that the same modality, non-contrast Computed Tomography DICOM images of adult patients and analysis of coronary artery calcification.

Technological Comparison

21 CFR 807.92(a)(6)

The technology utilized by the subject and predicate devices to provide information for coronary artery calcification analysis is the same as both utilize deep learning based algorithms.

Non-Clinical and/or Clinical Tests Summary & Conclusions

21 CFR 807.92(b)

The TeraRecon Cardiovascular.Calcification.CT device underwent a retrospective cohort study where ground truth was established and compared to the output of the device.

The ground truth data to be used is established based on the data management plan. At least 50% of the ground truth data is from the US divided between multiple locations. 422 adult patients are included in the cohort meeting following the inclusion/exclusion criteria: Adult patients (30 years and older), with a CT scan following a Calcium score CT scan protocol without contrast and coverage of the heart. Patient scans with CT artifacts that make the image unsuitable for the clinical use case, patients with previous and established ischemic cardiac diseases such as IMA, bypass grafts, stents and PTCS, scans with not enough slice coverage of the anatomy resulting in suboptimal imaging, pre-existing cardiac devices or electrodes, low dose CT's and CT contrast enhanced images were excluded from the bench testing.

For each study, annotator segments all coronary vessels and applies threshold to create calcification mask within vessels. 4 vessel classes:
• left main coronary artery (LM)
• left anterior descending coronary artery (LAD)
• left circumflex coronary artery (LCX)
• right coronary artery (RCA)
Each study will be processed by 3 different annotators.
Agatston classification: Acceptance criteria: TeraRecon Cardiovascular.Calcification.CT identify calcium masks accurately enough so that when the associated Agatston scores for the 4 Agatston classes, at >= 80% accuracy with a lower bound 95% confidence interval >= 75%. Please note that the TeraRecon Cardiovascular.Calcification.CT does not output Agatston scores. The Agatston classes of no evidence and minimal were combined due to a single pixel difference between the 2 groups and limited clinical value. The final calcification ground truth for the calcification segmentation masks is attained by majority vote among the segmentation results from the 3 annotators. Basically, a voxel will be part of final ground truth calcification mask if it is in at least 2 of the masks defined by the three annotators.

Revised Agatston Score Classes
• no evidence of CAD OR minimal: 0-10 calcium score
• mild: 11-100
• moderate: 101-400
• severe: >400
Our power analysis assumes 90-95% accuracy per class. Over 10K simulations we found a power of 93% to 99% per class when sample size was set to >=75 per class. Thus, the total power across the 4 classes was >80%. We used the Wilson binomial confidence interval. Accuracy acceptance criteria of 0.80 was chosen to be consistent with results found using similar AI in the literature (Ma 2019, de Vos 2017) and sufficient to improve prediction of CVD events (Naghavi 2024).
Vessel calcification classification
Acceptance criteria: TeraRecon Cardiovascular.Calcification.CT segments calcifications and classify them by vessel at >= 80% DICE with a lower bound 95% confidence interval >= 75%. The ground truth vessel of calcification is attained by majority vote among the 3 annotators (LM, LAD, LCX, RCA). Power analysis assuming 85% DICE shows sufficient power given the forementioned sample size.

Following the execution of the study, it was determined that the TeraRecon Cardiovascular.Calcification.CT device passed the acceptance criteria established in the study based on the following results:

The test results confirm that TeraRecon Cardiovascular.Calcification.CT provides accurate segmentation of calcified plaques within the coronary arteries both at the global level and within individual coronary branches (LAD, LCX, LM, RCA). Segmentation performance, measured by Dice similarity coefficient against expert annotations, consistently exceeded the predefined acceptance criteria (≥80% Dice with lower 95% CI ≥75%), demonstrating reliable identification of calcified plaques across the testing population. Furthermore, the device demonstrated robust segmentation and classification performance as indicated by Agatston categories (0–10, 11–100, 101–400, >400), with mean accuracies exceeding 94% and 95% CI lower bounds above 75%. Subgroup analyses confirmed that this performance is consistent across sex, age groups, vendors, and acquisition sites, supporting the robustness of the segmentation and classification output across different Agatston categories.

The test results support the conclusion that the TeraRecon Cardiovascular.Calcification.CT device is as safe and as effective as the predicate device cleared under K233211.