January 23, 2025

TeraRecon, Inc.
Michael Sosebee
Director, Regulatory Affairs and Quality Assurance
4309 Emperor Boulevard, Suite 310
Durham, North Carolina 27703

Re: K243158
Trade/Device Name: TeraRecon Aorta.CT (1.1.0)
Regulation Number: 21 CFR 892.2050
Regulation Name: Medical Image Management And Processing System
Regulatory Class: Class II
Product Code: QIH
Dated: September 30, 2024
Received: January 7, 2025

Dear Michael Sosebee:

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,

for

Jessica Lamb, Ph.D.
Assistant Director
Imaging Software Team
DHT8B: Division of Radiological 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)*

K243158

Device Name

TeraRecon Aorta.CT (1.1.0)

Indications for Use *(Describe)*

TeraRecon Aorta.CT is intended to provide an automatic 3D segmentation and label anatomical landmarks of the Aorta. The results of TeraRecon Aorta.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 Aorta.CT is a software as a medical device (SaMD) deployed as a containerized application. The device inputs are CT Angiography with 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 Aorta.CT is indicated to generate results from aortic CT Angiography scans taken of adult patients except patients with pre-existing aortic device, bicuspid aortic valve anomaly, aortic dissection, aortic rupture, and abdominal metallic devices. The device is not specific to any gender, ethnic group, or clinical condition.

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.

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TeraRecon Aorta.CT 1.1.0 510(k) Summary

K243158

510(k) Number:	K243158
Prepared on:	23Jan2025

Contact Details

Applicant Name:	TeraRecon, Inc.
Applicant Address:	4309 Emperor Boulevard, Suite 310 Durham NC 27703 United States
Applicant Contact Telephone:	+1 984-275-1090
Applicant Contact:	Mr. Michael Sosebee
Applicant Contact Email	msosebee@concertai.com

Device Name

Device Trade Name:	TeraRecon Aorta.CT (1.1.0)
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 Predicated Device

Predicate #:	K220039
Predicate Trade Name:	AutoSeg-H
Product Code:	LLZ

Device Description Summary

The TeraRecon Aorta.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 aorta and landmarks of important aortic anatomy. When TeraRecon Aorta.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 Aorta.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

TeraRecon Aorta.CT is intended to provide an automatic 3D segmentation and label anatomical landmarks of the Aorta. The results of TeraRecon Aorta.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 Aorta.CT is a software as a medical device (SaMD) deployed as a containerized application. The device inputs are CT Angiography with 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 Aorta.CT is indicated to generate results from aortic CT Angiography scans taken of adult patients except patients with pre-existing aortic device, bicuspid aortic valve anomaly, aortic dissection, aortic rupture, and abdominal metallic devices. The device is not specific to any gender, ethnic group, or clinical condition.

Indications for Use Comparison

Indications for Use (Subject Device) - TeraRecon Aorta.CT
TeraRecon Aorta.CT is intended to provide an automatic 3D segmentation and label anatomical landmarks of the Aorta. The results of TeraRecon Aorta.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 Aorta.CT is a software as a medical device (SaMD) deployed as a containerized application. The device inputs are CT Angiography with 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 Aorta.CT is indicated to generate results from aortic CT Angiography scans taken of adult patients except patients with pre-existing aortic device, bicuspid aortic valve anomaly, aortic dissection, aortic rupture, and abdominal metallic devices. The device is not specific to any gender, ethnic group, or clinical condition.

Indications for Use (Predicate Device) – AugoSeg-H, K220039
AutoSeg-H is medical imaging software that is intended to provide trained medical professionals with tools to aid them in reading, interpreting, reporting, and treatment planning. AutoSeg-H accepts DICOM compliant medical images acquired from imaging device (Computed Tomography).

AutoSeg-H provides the tools for specific analysis applications which provide custom UI, targeted measurements and reporting functions including:
- Coronary Artery Analysis for CT coronary arteriography images: which is intended for the qualitative and quantitative analysis of coronary arteries.
- Valve Analysis: which is intended for automatic extraction of the heart and aorta regions, automatic detection of the contour of the aorta and valves, measurement of the vicinity of the valves.
- 4-Chamber Analysis: which is intended for automatic extraction of the left atrium, left ventricle, right atrium, and right ventricle from CT.

Comparison of the Indications for Use:
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, Computed Tomography DICOM images and automated segmentation of the aorta are employed to provide similar device output.

Technological Comparison

	Subject Device TeraRecon Aorta.CT K243158	Predicate Device AutoSeg-H K220039	Comparison
Indications for Use	TeraRecon Aorta.CT is intended to provide an automatic 3D segmentation and label anatomical landmarks of the Aorta. The results of TeraRecon Aorta.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 Aorta.CT is a software as a medical device (SaMD) deployed as a containerized application. The device inputs are CT Angiography with 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 Aorta.CT is indicated to generate results from aortic CT Angiography scans taken of adult patients except patients with pre-existing aortic device, bicuspid aortic valve anomaly, aortic dissection, aortic rupture, and abdominal metallic devices. The device is not specific to any gender, ethnic group, or clinical condition.	AutoSeg-H is medical imaging software that is intended to provide trained medical professionals with tools to aid them in reading, interpreting, reporting, and treatment planning. AutoSeg-H accepts DICOM compliant medical images acquired from imaging device (Computed Tomography). AutoSeg-H provides the tools for specific analysis applications which provide custom UI, targeted measurements and reporting functions including: - Coronary Artery Analysis for CT coronary arteriography images: which is intended for the qualitative and quantitative analysis of coronary arteries. - Valve Analysis: which is intended for automatic extraction of the heart and aorta regions, automatic detection of the contour of the aorta and valves, measurement of the vicinity of the valves. - 4-Chamber Analysis: which is intended for automatic extraction of the left atrium, left ventricle, right atrium, and right ventricle from CT.	**Differences:** The subject device does not include functionality to provide professionals with tools to read, interpret, report or treatment plan. The predicate device provides analysis tools for coronary artery analysis and 4-chamber analysis that the subject device does not provide. The predicate device provides measurements of the vicinity of the cardiac valves which the subject device does not provide. The subject device includes landmarks of the aorta that the predicate device does not. The subject device indicates that it is not for use on images of adult patients with pre-existing aortic device, bicuspid aortic valve anomaly, aortic dissection, aortic rupture, and abdominal metallic devices. The predicate device does not mention similar non use scenarios. **Similarities:** The subject and predicate devices are both indicated for use with Computed Tomography (CT) DICOM images. The subject and predicate devices are both indicated for use on images of adult patients. The subject and predicate devices both provide segmentation results. **Summary:** The noted differences do not render the subject device NSE because the identified differences do not raise different safety and effectiveness questions. The similarities show that similar device output is provided based on the same technology utilized in the devices.
Modality	Computed Tomography (CT)	Computed Tomography (CT)	Same
Algorithm Technology	Supervised deep learning-based algorithms	Deep learning-based algorithms	Same

	Subject Device TeraRecon Aorta.CT K243158	Predicate Device AutoSeg-H K220039	Comparison
Device Outputs	DICOM Seg and DICOM CoF	Results in form of 2D Images, 3D Images, Information and Results	**Differences:** The predicate device outputs measurement results that are not available in the subject device. **Similarities:** Both the subject and predicate devices output results following the DICOM standard. **Summary:** The noted differences do not render the subject device NSE because the identified differences do not raise different safety and effectiveness questions. The similarities show that similar device output is provided based on the same technology utilized in the devices.
Installation Methods	Application installed on a computer	Application installed on a computer	Same

Non-Clinical and/or Clinical Tests Summary & Conclusions

The TeraRecon Aorta.CT device underwent a retrospective cohort study where ground truth was established and compared to the output of the device as described below:

At least 50% of the ground truth data is of US patients from 3 geographical regions in the United States. Each ground truth scan will also pass through the subject device. 170 adult patients are included in the cohort meeting the following inclusion/exclusion criteria: Patients must be 18 or older, must have had a CT Angiography scan for cardiac or CT Angiographic scan for abdomen or for both covering cardiac and abdominal aorta, and the validation data should be enriched with data from patients with clinical diagnosis of aortic dilation/aneurysm and/or aortic valve disease.

The following results will be compared between the ground truth and device results, Lumen Segmentation: Comparison of Aorta lumen segmentation results from the medical device to aorta lumen segmentation from ground truth. Aorta wall segmentation: The test will compare the results from ground truth to medical device output representing for aorta wall to wall segmentation. This aorta wall to wall segmentation includes aorta lumen + wall for the comparison. The lumen and aorta wall (including lumen) segmentations are important for extracting measurements that can be used by the clinicians for procedure planning. Landmarking results: The 22 anatomical landmarks for aorta will be compared from the device output to the ground truth.

For each CTA scan we will record aortic lumen segmentation DICE score and aorta segmentation DICE score for the subject device vs each of the ground truths. Our acceptance criteria for lumen and aorta segmentation accuracy are for average DICE score >= 80%.

For each CTA scan, we will also examine the subject device landmarking locations compared to each ground truth annotation. The Common Left and Right Iliac Arteries, Left and Right Femoral Arteries (4 landmarks) will be evaluated by whether or not the subject device correctly identified the vessel in accordance with ground truth. In a typical clinical workflow, these landmarks need only identify any point

in the center of the vessel, thus the identification of the overall anatomic location is of greatest importance, rather than exact location.

The remaining landmarks except for the aortic bifurcation (17 landmarks) will be assessed using Euclidean distance between ground truth annotation and medical device output locations. We will determine whether the Euclidean distance is within 5mm.

Finally, for the aortic bifurcation (1 landmark), the exact location is not clearly defined, and a general area is sufficient in typical clinical practice. We will determine whether the Euclidean distance is within 2cm compared to ground truth.

Our acceptance criteria for the landmarks are whether each of the 22 landmarks independently pass the class-specific criteria in 80% of the cases. To provide evidence of precision, we will assess whether the lower bound of the 95% exact binomial confidence interval (binom.confint from the R power library) is greater than or equal to 70% (~ acceptance level - 10%). A sample size of 100 CTA scans was chosen since during power simulations of 10,000 simulated runs, an actual case-wise pass rate of 90% resulted in power of 81% to pass all 24 tests after accounting for 30% loss of cases due to some landmarks being outside of field of view. Power calculation code displayed in appendix.

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

For testing the lumen and aorta segmentation, we selected 170 studies which matched the inclusion exclusion criteria. The final manufacturer distribution was 77 Siemens, 33 GE, 35 Philips, and 25 Canon. All collected datasets were checked and were found acceptable to use by a US board certified radiologist, who is currently practicing in the United States and reads similar scans.

Our acceptance criteria for lumen and segmentation is to confirm a mean DICE score of >=80%. The lumen segmentation results passed with a mean DICE score of 88%. The aorta segmentation results passed with a mean DICE score of 90%.

For testing the aorta landmarking, we selected 170 studies which matched the inclusion exclusion criteria, but we found that the number of landmarks outside the field of view was higher than expected: 40-45% actual vs 30% expected. The annotators were unable to provide annotations for these images, and we had a range of between 55-60 annotatable landmarks per landmark target. Additionally, sections of many images contained image artifacts which made annotation impossible. These artifacts included motion artifacts, occluded vessels, and lack of contrast in the aortic arch and heart. We increased the number of studies to achieve our target of 70 annotatable landmarks, according to our power calculations. We added 29 additional studies to the initial total. After adding 29 supplemental studies, we averaged 73 annotatable landmarks per landmark target with a minimum of 63. Thus, we stopped increasing the sample size.

Our acceptance is to assess whether each of the 22 landmarks independently pass evaluation in 80% of the cases. To provide evidence of precision we assess whether the lower bound of the 95% exact binomial confidence interval (binom.confint from the R power library) is greater than or equal to 70% (~ acceptance level - 10%). All landmarks passed the acceptance criteria, all 95% confidence intervals were at least 70%.

The test results support the conclusion that the TeraRecon Aorta.CT device is as safe, as effective and performs as well as the predicate device cleared under K220039.