



November 5, 2024

TeraRecon, Inc.
Alexis Ferrier
Regulatory Affairs Specialist
4309 Emperor Boulevard, Suite 310
Durham, North Carolina 27703

Re: K241312

Trade/Device Name: TeraRecon Cardiac.Chambers.MR (1.0.0)
Regulation Number: 21 CFR 892.2050
Regulation Name: Medical Image Management And Processing System
Regulatory Class: Class II
Product Code: QIH
Dated: October 10, 2024
Received: October 10, 2024

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,

 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

Indications for Use

Submission Number (if known)

K241312

Device Name

TeraRecon Cardiac.Chambers.MR (1.0.0)

Indications for Use (Describe)

This medical device is intended to segment Cardiac chambers as anatomical structures on contrast or non-contrast MR scans of adult patients that undergo Cardiac MR procedures. The algorithm is not specific to any gender or ethnic group or clinical conditions.

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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Tuesday, November 5, 2024

K241312

TeraRecon Cardiac.Chambers.MR 510(k) Summary

Applicant Name: TeraRecon, Inc.

Applicant Address: 4309 Emperor Boulevard, Suite 310 Durham, NC 27703 United States

Applicant Contact Telephone: 650.372.1100

Applicant Contact: Ms. Alexis Ferrier

Applicant Contact Email: afferrier@terarecon.com

Device Name: TeraRecon Cardiac.Chambers.MR (1.0.0)

Common Name: Medical Image Management and Processing System

Classification Name: Automated Radiological Image Processing System

Regulation Number: 892.2050

Product Code (s): QIH

Predicate Device: Circle Cardiovascular Imaging, Inc., cvi42 Auto Imaging Software Application, K213998

Predicate Device Regulation Number: 21 CFR 892.2050

Predicate Device Product Code: QIH, LLZ

This predicate has not been subject to a design-related recall.

Device Description Summary:

The TeraRecon Cardiac.Chambers.MR algorithm is comprised of two components:

1. The TeraRecon Cardiac.Chambers.MR for Cine-ax
2. The TeraRecon Cardiac.Chambers.MR De-ax

1: The TeraRecon Cardiac.Chambers.MR for Cine-ax

The TeraReconCardiac.Chambers.MR algorithm for Cine-ax is an image processing software device that can be deployed as a containerized application (e.g., Docker container).

The TeraRecon Cardiac.Chambers.MR algorithm for Cine-ax automatically detects and identifies the heart location and derives left ventricular (LV) and right ventricular (RV) myocardium segmentation on DICOM-compliant cardiovascular MR images of different cardiac imaging sequences.

The TeraRecon Cardiac.Chambers.MR for Cine-ax algorithm performs a segmentation (or tracing) around the epicardial border as well as the endocardial border wall. For the RV the algorithm segments the endocardial border wall.

2: The TeraRecon Cardiac.Chambers.MR for De-ax

The TeraReconCardiac.Chambers.MR algorithm for De-ax is an image processing software device that can be deployed as a containerized application (e.g., Docker container).

The TeraRecon Cardiac.Chambers.MR algorithm for De-ax automatically detects and identifies the heart location and derives left ventricular (LV) myocardium segmentation on DICOM-compliant cardiovascular MR images of different cardiac imaging sequences.

The TeraRecon Cardiac.Chambers.MR for De-ax algorithm performs a segmentation (or tracing) around the epicardial border as well as the endocardial border wall.

Intended Use/ Indications for Use:

This medical device is intended to segment Cardiac chambers as anatomical structures on contrast or non-contrast MR scans of adult patients that undergo Cardiac MR procedures. The algorithm is not specific to any gender or ethnic group or clinical conditions.

Indications for Use Comparison:

Indications for Use (Subject Device) TeraRecon Cardiac.Chambers.MR

Intended Use:

TeraRecon Cardiac.Chambers.MR automatically segments cardiac chambers inner and outer walls of the left ventricle and inner wall of the right ventricle. The input files for the device are contrast or non-contrast images acquired via DICOM compliant MR imaging devices. The outputs are DICOM files that may be utilized by other DICOM-compliant systems and results, such as TeraRecon's Intuition system or other image viewing systems like PACS.

The TeraRecon Cardiac.Chambers.MR Algorithm results are designed for use by trained healthcare professionals and are intended to assist the physician in diagnosis or treatment planning. The physician is responsible for making all final patient management decisions.

Indications for Use:

This medical device is intended to segment Cardiac chambers as anatomical structures on contrast or non-contrast MR scans of adult patients that undergo Cardiac MR procedures. The algorithm is not specific to any gender or ethnic group or clinical conditions.

Indications for Use (Predicate Device) - cvi42 Auto Imaging Software Application, K213998

cvi42 Auto is intended to be used for viewing, post-processing, qualitative and quantitative evaluation of cardiovascular magnetic resonance (MR) and computed tomography (CT) images in a Digital Imaging and Communications in Medicine (DICOM) Standard format.

It enables a set of tools to assist physicians in qualitative assessment of cardiac images and quantitative measurements of the heart and adjacent vessels; perform calcium scoring; and to confirm the presence or absence of physician-identified lesion in blood vessels.

The target population for cvi42 Auto's manual workflows is not restricted; however, cvi42 Auto's semi-automated machine learning algorithms are intended for an adult population.

cvi42 Auto shall be used only for cardiac images acquired from an MR or CT scanner. It shall be used by qualified medical professionals, experienced in examining and evaluating cardiovascular MR or CT images, for the purpose of obtaining diagnostic information as part of a comprehensive diagnostic decision-making process.

Comparison of the Indications for Use:

The differences between the two indications for use statements do not undermine the substantial equivalence as the differences are summarized as additional functionality offered by the predicate device in comparison to the subject device. These differences do not raise different safety and effectiveness questions in the subject device. The similarities in the two

indications for use show the same technology, supervised deep learning based algorithms for segmentation of cardiac anatomical structures from Magnetic Resonance (MR) DICOM images acquired from adult patients.

Technological Comparison:

The technology utilized by both the subject and predicate device to provide segmentation of cardiac anatomical structures is the same as both devices utilize supervised deep learning algorithms.

Non-Clinical and/or Clinical Tests Summary & Conclusions

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

The validation ground truth data set (cohort) was comprised of 100 adult patients, 50 for the Cine-ax algorithm and 50 for the De-ax algorithm.

Cine-ax algorithm

The validation ground truth data set (cohort) of 50 adult patients for the Cine-ax algorithm met the following inclusion/exclusion criteria: 1) Patients must be 18 years or older, must have magnetic resonance scan 4D multiphase balance gradient echo (GRE) covering the heart with a GE, Philips or Siemens scanner, and 2) the data set should be with or without contrast enhancement, with a scan orientation of the LV short axis, ECG-gating and breath sync. The matrix size should be [125:512]x [125:512], with a slice thickness of [6:10] mm and interslice gap of [0:2] mm. Any data that contained artifacts including, wrapping, ghosting (such as motion, respiratory, and flow), chemical shifts, dark rim, phase, radio frequency interference, slow flow, metal, 3T inherent artifacts (higher magnet strength artifacts) or any other cause that makes the sequence unsuitable to support the diagnosis was removed from the validation dataset.

It is ensured that patient data received for training of the algorithm is from different sites than the validation data utilized for this study. Three MR equipment manufacturers are included in this cohort to show generalizability. The three vendors were selected based on the market share data. The market research data has shown coverage of 74% of scanners in US with these three manufacturers- GE, Siemens, and Philips . 82% of the studies came from United States, the rest of 18% came from Europe which has close to similar patient demographics as the United States population.

All collected datasets were reviewed by a board certified radiologist practicing in the United States with experience in reviewing cMR studies. The radiologists evaluated whether each cMR scan met the inclusion/exclusion criteria, and if the study did not meet the inclusion exclusion criteria then the study was replaced.

The next phase of the study was to collect and compare the TeraRecon Cardiac.Chambers.MR cine-ax algorithm output to the created ground truth as described below.

For each dataset, the LV Myocardium DICE score, LV chamber DICE score, RV Chamber DICE score was recorded for the subject device vs. ground truth.

De-ax algorithm

The validation ground truth data set (cohort) of 50 adult patients for the De-ax algorithm met the following inclusion/exclusion criteria: 1) Patients must be 18 years or older, must have magnetic resonance scan 3D multi-slice IR single phase covering the heart with a GE, Philips or Siemens scanner, and 2) the data set should be with a scan orientation of the LV short axis, ECG-gating and breath sync. The matrix size should be [125:512]x [125:512], with a slice thickness of [6:10] mm and interslice gap of [0:2] mm. Any data that contained burned images with the wrong inversion time, no contrast or that contained artifacts including, wrapping, ghosting (such as motion, respiratory, and flow), chemical shifts, dark rim, phase encoded, radio frequency interference, slow flow, metal, 3T inherent artifacts (higher magnet strength artifacts) or any other cause that makes the sequence unsuitable to support the diagnosis was removed from the validation dataset.

It is ensured that patient data received for training of the algorithm is from different sites than the validation data utilized for this study. Three MR equipment manufacturers are included in this cohort to show generalizability. The three vendors were selected based on the market share data. The market research data has shown coverage of 74% of scanners in US with these three manufacturers- GE, Siemens, and Philips . 82% of the studies came from United States, the rest of 18% came from Europe which has close to similar patient demographics as the United States population.

All collected datasets were reviewed by a board certified radiologist practicing in the United States with experience in reviewing cMR studies. The radiologists evaluated whether each cMR scan met the inclusion/exclusion criteria, and if the study did not meet the inclusion exclusion criteria then the study was replaced.

The next phase of the study was to collect and compare the TeraRecon Cardiac.Chambers.MR de-ax algorithm output to the created ground truth as described below.

For each dataset, we will derive the left ventricle chamber (LV) and left ventricle myocardium (MYO). The LV is defined as the voxels within the left ventricle endocardium. The left ventricle MYO is defined as the voxels between the endocardium and epicardium. We will record LV segmentation DICE score MYO segmentation DICE score for subject device vs each of the ground truths. Our acceptance criteria for LV and MYO independently was based on literature review of cardiac MRI left ventricle segmentation accuracy.

Completion of the evaluation study showed that TeraRecon Cardiac.Chambers.MR device passed the established acceptance criteria for both algorithms based on the following results:

The results of the Cine-ax algorithm showed the LV Myocardium mean DICE scores for were within the acceptance criteria at 0.82 (0.81,0.83) and within the 95% confidence interval (CI). The results indicated the LV Chambers mean DICE Scores were within the acceptance criteria and were at or greater than 0.90 (0.89, 0.91) within the 95% confidence interval, , and the mean DICE Score for RV Chamber was 0.84 (0.82, 0.85) and thus within the 95% confidence interval and passing the DICE limit score. When broken down by gender (M/F), age (<41Y, 41-60Y, >60Y), pathology (Y/N, and Ventricular hypertrophy, Heart failure) and Modality (GE, Philips, Siemens), contrast vs. no-contrast, and magnetic field strength, the LV Myocardium, LV Chamber and RV Chamber DICE scores still are above the respective thresholds set in the clinical validation protocol and the 95% confidence interval were again entirely above the threshold margins. Therefore, the algorithm not only passes the

acceptance criteria delineated in the Clinical Validation Plan Document in aggregate, but the DICE score is higher than the prescribed threshold for each gender, manufacturer, clinical site, contrast and magnetic field strength.

The results of the De-ax algorithm showed the LV myocardium mean DICE scores were within the acceptance criteria at 0.79 (0.75, 0.83), and the LV Chamber mean DICE scores were within the acceptance criteria at 0.88 (0.84, 0.92). When broken down by gender (M/F), age (<41Y, 41-60Y, >60Y), pathology (Y/N, and Ventricular hypertrophy, Heart failure) and Modality (GE, Philips, Siemens), and magnetic field strength, the LV Myocardium, and LV Chamber DICE scores .results were within the 95% confidence interval and entirely above threshold margins set in the Clinical Evaluation Protocol. Therefore, the algorithm not only passes the acceptance criteria delineated in the Clinical Validation Plan Document in aggregate, but the DICE score is higher than the prescribed threshold for each manufacturer, clinical site and gender.

The TeraRecon Cardiac.Chambers.MR device is as safe, as effective as the predicate device.