TeraRecon Inc.,
Megha Jain
QARA Manager
4000 East 3rd Avenue, Suite 200
FOSTER CITY, CA 94404

September 24, 2018

Re: K180916
Trade/Device Name: iNtuition-T1 Mapping and T2/T2* Mapping
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: Class II
Product Code: LLZ
Dated: August 24, 2018
Received: August 27, 2018

Dear Megha Jain:

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 (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 located 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.

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 803) for

devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/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

Robert A. Ochs, Ph.D.
Director
Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K180916

Device Name
iNtuition-T1 Mapping and T2/T2* Mapping

Indications for Use *(Describe)*
iNtuition-T1 Mapping and T2/T2* Mapping are software modules that support the derivation and quantification of T1, T2 and T2* values from MR DICOM image pixel intensities and header information. The quantification of these parameters can be used to characterize tissues. Support is provided to overlay the T1, T2, and T2* values using colormaps on related MR images.

Support is provided for using different colormaps to overlay different ranges of T1, T2 or T2* values and restrict the overlay to region of interest on the images. The MR images can be of simple planar scan like a single slice or volumetric or 4D scans of a body part. iNtuition-T1 Mapping and T2/T2* Mapping are iNtuition software features that can be used in multiple workflows or be used as basic tools for cardiac functionality. Additionally, the overlaid images can be captured and forwarded to other systems using standards such as DICOM or http protocol. Quantitative analysis is derived and available as text and graphical display.

iNtuition- T1 Mapping and T2/T2* Mapping qualitative results and visualization can be used in a clinical setting on MR images of an individual patient and can be used to support the clinical decision making for the diagnosis of the patient. iNtuition- T1 Mapping and T2/T2* Mapping are designed for use by healthcare professionals and are intended to assist the physician in diagnosis, who is responsible for making all final patient management decisions.

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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Date of Summary: 24-Aug-2018

510(k) Summary of Safety and Effectiveness (As required by 21 CFR 807.92(c))	**iNtuition-T1 Mapping and T2/T2* Mapping**

Submitter/: TeraRecon Inc.
Applicant/ Sponsor 4000 E 3rd Ave, Suite 200
Foster City, CA 94404

Establishment Registration #: 2954793

Contact Person: Megha Jain
QARA Manager
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Device Information:

510k #:	K180916
Name of Device:	iNtuition-T1 Mapping and T2/T2* Mapping
Model No:	4.4
Common Name:	Medical Imaging System
Classification Name:	§ 892.2050, Picture Archiving and Communication System. ProCode: LLZ
Classification Panel:	Radiology
Device Classification:	Class II device

Substantial Equivalence:

iNtuition-T1 Mapping and T2/T2* Mapping, as addressed in this premarket notification, is substantially equivalent to the following commercially available device:

MR-CT VVA (K140587): QMass T2/T2star Analysis module and M-TOM: QMass T1 analysis module, Medis Medical Imaging Systems, b.v.

Indications for Use:

iNtuition-T1 Mapping and T2/T2* Mapping are software modules that support the derivation and quantification of T1, T2 and T2* values from MR DICOM image pixel intensities and header information. The quantification of these parameters can be used to characterize tissues. Support is provided to overlay the T1, T2, and T2* values using colormaps on related MR images.

Support is provided for using different colormaps to overlay different ranges of T1, T2 or T2* values and restrict the overlay to region of interest on the images. The MR images can be of simple planar scan like a single slice or volumetric or 4D scans of a body part. iNtuition-T1 Mapping and T2/T2* Mapping are iNtuition software features that can be used in multiple workflows or be used as basic tools for cardiac functionality. Additionally, the overlaid images can be captured and forwarded to other systems using standards such as DICOM or http protocol. Quantitative analysis is derived and available as text and graphical display.

iNtuition- T1 Mapping and T2/T2* Mapping qualitative results and visualization can be used in a clinical setting on MR images of an individual patient and can be used to support the clinical decision making for the diagnosis of the patient. iNtuition- T1 Mapping and T2/T2* Mapping are designed for use by healthcare professionals and are intended to assist the physician in diagnosis, who is responsible for making all final patient management decisions.

Device Description:

iNtuition-T1 Mapping and T2/T2* Mapping is an optional image post-processing module, part of iNtuition (K121916), which is software only device generally used with the off-the-shelf hardware, offered in various configuration, with the simplest configuration being a stand-alone workstation capable of image review, communications, archiving, database maintenance, remote review, reporting and basic 3D capabilities. It can also be configured as a server with some, all, or none of its optional features disabled. Whether provided as a workstation or a server, the iNtuition software is designed to provide access by a local user physically sitting at the computer hosting the iNtuition server software, and/or by one or more remote users who concurrently connect to the server using a freely-downloadable thin client application or through a zero-footprint web viewer (with conference capabilities) over local network or internet.

iNtuition-T1 Mapping and T2/T2* Mapping feature can derive quantitative values from intensities and header information of specific MR scan sequences that are specifically coded to enable such derivation (such as Look-Locker and MOLLI for T1.) The quantification of these parameters can be used to derive clinical value such as T2*.. Post-processing such as computation of statistics like volume, area, min/max or various combinations of the derived values, over regions of interests or overlay the derived values using a colormap on related images or a region of the images. The region of interests can be defined by the user through manual, semi-automatic or automatic segmentation techniques provided by iNtuition. The derivation and post-processing can be used with planar, volumetric or 4D scan sequences for cardiac functionality.

iNtuition-T1 Mapping and T2/T2* Mapping is an iNtuition based optional features, and employ all standard features offered by iNtuition such as convenient image manipulation tools like drawing region of interest, manual or automatic segmentation of structures and tools that support creation of a report, transmitting and storing this report in digital form, and tracking historical information about the studies analyzed by the software.

This device is intended only to assists the operator in making decisions. The software is not intended to replace the skill and judgment of a qualified medical practitioner and should only be used by people that have been trained in the software's function (iNtuition), capabilities and limitations. The device is intended to provide supporting analytical tools to a physician, to speed decision-making and to improve communication, but the physician's judgment is paramount and it is normal practice for physicians to validate theories and treatment decisions multiple ways before proceeding with a risky course of patient management.

iNtuition-T1 Mapping and T2/T2* Mapping modules may be sold separately or as an extension of iNtuition.

Technological Characteristics:

iNtuition-T1 Mapping and T2/T2* Mapping will be marketed as a software only solution for the end-user (with recommended off-the-shelf hardware components).

Summary of Non-Clinical Performance Tests:

There are no applicable FDA mandated performance standards for this device. However, voluntary standards such as DICOM and various in-house standard operating procedures are in place and utilized in the development and production of the software. These include:

- ISO 14971 Medical devices – Application of risk management to medical devices
- IEC 62304 Medical device software – Software life cycle processes
- NEMA-PS 3.1- PS 3.20 Digital Imaging and Communications in Medicine (DICOM)
- Guidance for Industry and FDA Staff – Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices

Software verification and validation was completed in accordance with internal processes.

Verification and Validation tests have been performed to address intended use, the technological characteristics claims, requirement specifications and the risk management results.

Risk management is ensured via risk analysis, which is used to identify and mitigate potential hazards beginning early in the design cycle and continuing throughout the development of the product. These potential hazards are controlled via software development, verification and validation testing. Furthermore, the operators are healthcare professionals familiar with and responsible for making all final patient management decisions.

In all material aspects, iNtuition-T1 Mapping and T2/T2* Mapping is substantially equivalent to the predicate device. Performance testing was carried out according to internal company procedures. Software testing and validation were done according to written test protocols established before testing was conducted. Test results were reviewed by designated technical professionals before software proceeded to formalize after ensuring that the software fully satisfies all expected and previously defined system requirements and features. Test results support the conclusion that actual device performance satisfies the design intent and is equivalent to its predicate device.

Summary of Clinical Performance Tests:

The subject of this traditional 510k notification, iNtuition-T1 Mapping and T2/T2* Mapping, did not require clinical studies to show safety and effectiveness of the software.

General Safety and Effectiveness Concerns:

The introduction of iNtuition-T1 Mapping and T2/T2* Mapping has no significant concerns of safety and efficacy. iNtuition-T1 Mapping and T2/T2* Mapping in comparison with its predicate device has similar intended use and technological characteristics.

Instructions for use are included within the device labeling, and the information provided will enable the user to operate the device in a safe and effective manner.

Conclusion:

iNtuition-T1 Mapping and T2/T2* Mapping as described in this premarket notification has similar intended use and technical characteristics to the predicate device listed above. These devices are substantially equivalent in terms of basic design, features and intended use.

iNtuition-T1 Mapping and T2/T2* Mapping is an iNtuition (K121916) based optional features, and employ all standard features offered by iNtuition such as convenient image manipulation tools like drawing region of interest, manual or automatic segmentation of structures and tools that support creation of a report, transmitting and storing this report in digital form, and tracking historical information about the studies analyzed by the software.

In summary, TeraRecon, Inc. is of the opinion that iNtuition-T1 Mapping and T2/T2* Mapping does not include any new potential safety or effectiveness risks and is substantially equivalent to and performs as well as the predicate device.