DEC 2 4 2013
K131447

TERARECON

Date of Summary: November 14, 2013

510(k) Summary of Safety and Effectiveness (As required by 21 CFR 807.92(c))	**iNtuition**

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

Establishment Registration #: 2954793

Contact Person: Emilly Tojima Nurthen
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Device Information:

Name of Device:	iNtuition – TDA, TVA, Parametric Mapping
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 – TDA, TVA, Parametric Mapping, as addressed in this premarket notification, is substantially equivalent to the following commercially available devices:

- Aquarius Workstation (K011142)
- AquariusAPS Server (K061214)
- LEONARDO syngo Cardiology Workstation (Argus) (K042203)
- LEONARDO (K040970)
- Syngo.CT Cardiac Function (K110366)
- CT Perfusion 4 (K052839)
- Syngo.MR Neurology (K121459)

iNtuition TDA has similar technological characteristics to the Aquarius Workstation, AquariusAPS Server and CT Perfusion 4, with added MR modality support as included in Syngo.MR Neurology.

iNtuition TVA has similar technological characteristics to the Aquarius Workstation, with improvements and additional features. These additional features include MR modality support

and right ventricle analysis (CT, MR) which are included in the Leonardo, Leonardo Argus and Syngo.CT Cardiac Function (excludes MR).

In comparison to AquariusAPS, iNtuition Parametric Mapping has improved visual appearance and additional color display options.

Indications for Use:

iNtuition-TDA, TVA, and Parametric Mapping are software modules which supports assessment of time-dependent behavior of image intensity, density, dimensions or volume of regions of interest over time, for volumetric or planar dynamic image types such as CT or MR. Parametric mapping tools encode in color various parameters derived from the temporal or spatial characteristics of the planar or volumetric data.

Support is provided for digital image processing to derive metadata or new images from input image sets, for internal use or for forwarding to other devices using the DICOM protocol. Image processing tools are provided to extract metadata to derive parametric images from combinations of multiple input images.

iNtuition-TDA, TVA and Parametric Mapping are iNtution-based software features with dedicated workflows and basic tools and thus support post-processing, displaying and manipulation of reports and medical images from acquisition devices and visualization in 2D, 3D and 4D for single or multiple datasets, or combinations thereof.

iNtuition-TDA, TVA, Parametric 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 – TDA, TVA, Parametric Mapping are post-processing modules, part of iNtuition, which is a software device generally used with off-the-shelf hardware, offered in various configurations, 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. A fully-configured iNtuition system is capable of various image processing and visualization functions to support the physician in medical image reviewing.

iNtuition – TDA, TVA, Parametric Mapping intended used is to provide solutions to various medical image analysis and viewing problems, which come about as modalities generate more and more images. They also support image distribution over networks, and are DICOM compliant.

iNtuition Time-Dependent Analysis (TDA) and Time-Volume Analysis (TVA) features can obtain quantitative information relating to the evolution of the intensity, density or

dimensions of certain regions of CT, MR or other images over time. Statistical analysis such as a histogram representation of the image density values in an image is supported, and analysis of changes in volume over time from multi-phase volumetric images; for example, ejection fraction and stroke volume measurement calculation can be performed using the Time-Volume Analysis tools.

iNtuition Parametric Mapping tools encode in color various parameters derived from the temporal or spatial characteristics of the planar or volumetric data.

iNtuition – TDA, TVA and Parametric Mapping are iNtuition-based optional features, and employ all standard features offered by iNtuition, such as convenient tools to support creation of a report, transmitting and storing this report in digital form, and tracking historical information about the studies analyzed with the software.

These three modules can be sold separately or as a part of the bigger iNtuition package.

Technological Characteristics:
iNtuition-TDA, TVA, Parametric Mapping will be marketed as iNtuition-based software only solution for the end-user (with recommended hardware requirements).

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

In all material aspects, iNtuition-TDA, TVA, Parametric Mapping is substantially equivalent to the predicate devices. 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 devices.

Summary of Clinical Performance Tests:
The subject of this traditional 510k notification, iNtuition-TDA, TVA, Parametric Mapping, did not require clinical studies to show safety and effectiveness of the software.

General Safety and Effectiveness Concerns:
The introduction of iNtuition-TDA, TVA, Parametric Mapping has no significant concerns of safety and efficacy. iNtuition-TDA, TVA, Parametric Mapping in comparison with their

predicate devices are iNtuition-based software modules which have the same 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.

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.

Conclusion:

iNtuition-TDA, TVA, Parametric Mapping as described in this premarket notification have the same intended use and similar technical characteristics to the predicate devices listed above. These devices are substantially equivalent in terms of basic design, features and intended use.

In summary, TeraRecon, Inc. is of the opinion that iNtuition-TDA, TVA, Parametric Mapping are iNtuition-based software modules which does not include any new potential safety or effectiveness risks and are substantially equivalent to and perform as well as the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

December 24, 2013

TERARECON
EMILLY TOJIMA NURTHEN
REGULATORY AFFAIRS MANAGER
4000 E 3RD AVE STE 200
FOSTER CITY CA 94404

Re: K131447
Trade/Device Name: iNtuition - TDA, TVA, Parametric Mapping
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: LLZ
Dated: November 29, 2013
Received: December 2, 2013

Dear Ms. Nurthen:

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. 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.

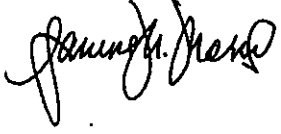
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 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 the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,



Janine M. Morris
Director
Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

Indications for Use

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Prescription Use ___X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of Center for Devices and Radiological Health (CDRH)