TeraRecon, Inc.
℅ Megha Jain
QARA Manager
4000 East, 3rd Ave, Suite 200
FOSTER CITY CA 94402

July 12, 2019

Re: K191585
Trade/Device Name: iNtuition-Structural Heart Module
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: Class II
Product Code: LLZ
Dated: June 11, 2019
Received: June 14, 2019

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/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 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 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

Thalia T. Mills, Ph.D.
Director
Division of Radiological Health
OHT7: Office of In Vitro Diagnostics
and 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K 191585

Device Name

iNtuition - Structural Heart Module 4.4

Indications for Use *(Describe)*

iNtuition-Structural Heart Module is a software solution that is intended to assist Cardiologists, Radiologists and Clinical Specialists with the visualization and measurements of structures of the heart and vessels.

iNtuition-Structural Heart Module enables the user to:
- Visualize and measure (diameters, lengths, angles, areas and volumes) structures of the heart and vessels for pre-operative planning and sizing for cardiovascular interventions and surgery, and for post-operative evaluation.
- Quantify calcium (volume, density)

iNtuition-Structural Heart Module has the following tools and features that facilitate:
- Automatic and manual centerline detection.
- Segmentation of cardiovascular structures.
- Measurement tools (diameters, lengths, areas, volumes, angles) for the dimensions of vessels and structures.
- Calcium quantification and scoring.
- Various visualization techniques: 2D/3D/4D visualization, MPR, Curved MPR, Stretched MPR, MIP, MinIP, Raysum and MAR.
- Capture and Report.

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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K191585

Date of Summary: 09 July 2019

510(k) Summary of Safety and Effectiveness (As required by 21 CFR 807.92(c))	iNtuition-Structural Heart Module

Submitter: TeraRecon, Inc.
Applicant: 4000 E 3rd Ave, Suite 200
Sponsor: Foster City, CA 94402
Establishment:
Registration#: 2954793

Contact erson: Magha Jain
QARA Manager
Ph: 650 -372-1100
Fax: 650 -372-1101
Email: mjain@terarecon.com

Device Information:

Name of Device:	iNtuition-Structural Heart Module
Common Name:	Medical Imaging System
Classification Name:	§ 892.2050, Picture Archiving and Communications System
Product Code:	LLZ
Classification Panel:	Radiology
Device Classification:	Class II

Predicate Devices::

- 3mensio Workstation (K153736) (Primary predicate device)
- iNtuition (K121916) (Secondary predicate device)

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- Various visualization techniques: 2D/3D/4D visualization, MPR, Curved MPR, Stretched MPR, MIP, MinIP, Raysum and MAR.
- Capture and Report.

Device Description:

iNtuition-Structural Heart Module is an optional image post-processing software module using iNtuition (K121916) standard features and part of its optional features. It is a software device generally used with the 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, or with all, or none of its optional features.

Whether provided as a workstation or a server, the iNtuition-Structural Heart Module 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 concurrentlyconnect 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-Structural Heart Module is iNtuition (K121916) based optional feature and employs all standard features offered by iNtuition such as convenient image manipulation tools like drawing of region of interests, manual and automatic segmentation of structures, image assessment and measurement tools – linear, diameter, perimeter, angle, area and volume and tools that support the creation of reports, transmitting and storing this report in digital form and tracking historical information about the studies analyzed by the software. iNtuition Vessel analysis and calcium scoring features are utilized to support automatic and manual centerline extraction and analysis and calcium quantification.

iNtuition-Structural Heart Module:

- Supports the visualization and quantification of coronary vessels and cardiac structures for anatomic and pre- or post-operative evaluations through guided clinical workflows.
- Enables the assessment and measurement of different structures of the heart, e.g. aorta, aortic valves, mitral valve, pulmonic valve, atria and atrial appendages, and ventricles.
- Provides analysis of the feasibility of a transapical, transfemoral or subclavian approach to structures for replacement or repair procedures via 3D measurements.
- Uses the same iNtuition (K121916) Vessel Analysis and Calcium modules.Enables

assessment and measurement of vessels and can help identify calcifications, aneurysms and other anomalies to quickly and reliably prepare for various types of vascular procedures.Supports the creation, transmission and storage of a report in digital form. It can also track historical information about the studies analyzed by the software.Displays results analysis, that can be printed as hardcopy or saved in a variety of formats to a hard disk, network, PACS system or CD/DVD/USB.

Comparison Technological Characteristics:

A comparison of the technological characteristics of the predicates and subject device is given in the table below:

	New Device	Predicate Device (Secondary)	Predicate Device (Primary)
Device Name	iNtuition-Structural Heart Module	iNtuition	3mensio Workstation
Manufacturer	Terarecon, Inc.	Terarecon, Inc.	Pie Medical Imaging
510(k) Number	K191585	K121916	K153736
Indication for Use			
Indications for Use	iNtuition-Structural Heart Module is a software solution that is intended to assist Cardiologists, Radiologists and Clinical Specialists with the visualization and measurements of structures of the heart and vessels. iNtuition-Structural Heart Module enables the user to: - Visualize and measure (diameters, lengths, angles, areas and volumes) structures of the heart and vessels for pre- operative planning and sizing for cardiovascular interventions and surgery, and for post- operative evaluation. - Quantify calcium (volume, density) iNtuition-Structural Heart Module has the following tools and features that facilitate: Automatic and manual centerline detection. Segmentation of cardiovascular structures.	- To receive, store, transmit, post- process, display and allow manipulation of reports and medical images from acquisition devices, including optical or other non-DICOM format images, DICOM images with modality type XA, US, CR, DR, SPECT, NM and MG, and images from volumetric medical scanning devices such as EBT, CT, PET or MRI. To provide access to images derived data and derived images via client-server software, web browser and mobile technology. - Visualization in 2D/3D and 4D are supported for single or multiple datasets. or combinations thereof. Tools are provided to define and edit paths through structures such as center lines, which may be used to analyze cross- sections of structures, or to provide flythrough visualizations rendered along such a centerline.	3mensio Workstation enables visualization and measurement of structures of the heart and vessels for: - Pre-operational planning and sizing for cardiovascular interventions and surgery - Postoperative evaluation - Support of clinical diagnosis by quantifying dimensions in coronary arteries - Support of clinical diagnosis by quantifying calcifications (calcium scoring) in the coronary arteries To facilitate the above, the 3mensio Workstation provides general functionality such as: Segmentation of cardiovascular structures - Automatic and manual centerline detection - Visualization and image-reconstruction techniques: 2D review, Volume Rendering, MPR, Curved MPR, Stretched CMRP,

	Measurement tools (diameters, lengths, areas, volumes, angles)	Segmentation of regions of interest and quantitative analysis tools are provided, for images of vasculature, pathology and morphology, including distance, angle, volume, histogram, ratios thereof, and tracking of quantities over time. A database is provided to track and compare results using published comparison techniques such as RECIST and WHO. Calcium scoring for quantification of atherosclerotic plaque is supported.	Slabbing, MIP, AIP, MinIP

	New Device	Predicate Device (Secondary)	Predicate Device (Primary)
	for the dimensions of vessels and structures. Calcium quantification and scoring. Various visualization techniques: 2D/3D/4D visualization, MPR, Curved MPR, Stretched MPR, MIP, MinIP, Raysum and MAR. Capture and Report.	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, such as temporal phases, or images co-located in space but acquired with different imaging parameters, such as different MR pulse sequences, or different CT image parameters (e.g. dual energy). iNtuition is designed for use by healthcare professionals and is intended to assist the physician in diagnosis, who is responsible for making all final patient management decisions. Interpretation of mammographic images or digitized film screen images is supported only when the software is used without compression and with an FDA-Approved monitor that offers at least 5Mpixel resolution and meets other technical specifications reviewed and accepted by the FDA. iNtuitionMOBILE provides wireless and portable access to medical images. This device is not intended to replace full workstations and should be used only when there is no access to a workstation. Not intended for diagnostic use when used via a web browser or mobile device.	Measurement and annotation tools Reporting tools

Technical Characteristics			
Data Type	- CT, MR, Nuc, PET, Angio, US/Echo, SPECT, - CR/DR Review - 2D, 3D, 4D Medical Image review including cine play	- CT, MR, Nuc, PET, Angio, US/Echo, SPECT, CR/DR Review - 2D, 3D, 4D Medical Image review including cine play	- CT data in DICOM format (vendor independent)
Input Patient Data	- Manual through keyboard/mouse - Command line interface	- Manual through keyboard/mouse - Command line interface	- Manual through keyboard/mouse - Command line interface

Study list functionality	- Importing - Exporting - Deleting - Search - Anonymization	- Importing - Exporting - Deleting - Search - Anonymization	- Exporting - Deleting - Anonymizing (no automatic deletion of original patient data) - Search
Centerline Extraction and	- Automatic and manual centerlines - Centerline edits and refinements. - Vessel Analysis - Automatic and manual segmentation of structures - Segmentation editing	- Automatic and manual centerlines - Centerline edits and refinements. - Vessel Analysis - Automatic and manual segmentation of structures - Segmentation editing	- Realign orthogonal MPR's - Segmentation toolset: - Automatic segmentation - Automatic centerline - Manual centerline - Centerline editing - Undo/Redo operations - Volume sculpting
Image Assessment	- Linear (length, diameter, perimeter), distance pair, angular and ROI measurements - Area measurements - Volume measurements including volumetric histogram, VOI and TVA for Time Volume Analysis for heart chamber segmentation and analysis - C-arm angulation calculation - Text and arrow annotations - Anatomy ID (Landmark Label Selection) - Calcium scoring for assessment of calcium in the aortic root - Calcium scoring for assessment of calcium in the coronary arteries - Segmentation and analysis of coronary artery tree centerline - Synchronized side-by-side review - Synchronized center of rotation viewing - Findings workflow for temporal correlative analysis - 2D/3D Batch movie tool and export	- Linear (length, diameter, perimeter), distance pair, angular and ROI measurements - Area measurements - Volume measurements including volumetric histogram, VOI and TVA for Time Volume Analysis for heart chamber segmentation and analysis - C-arm angulation calculation - Text and arrow annotations - Anatomy ID (Landmark Label Selection) - Calcium scoring for assessment of calcium in the aortic root - Calcium scoring for assessment of calcium in the coronary arteries - Segmentation and analysis of coronary artery tree centerline - Synchronized side-by- side review - Synchronized center of rotation viewing - Findings workflow for temporal correlative analysis - 2D/3D Batch movie tool and export	- Linear (length and diameter), angular and ROI measurements - Volume measurements - C-arm angulation calculation - Text and arrow annotations - Calcium scoring for assessment of calcium in the aortic root - Calcium scoring for assessment of calcium in the coronary arteries - Segmentation and analysis of coronary artery tree centerline

	New Device	Predicate Device (Secondary)	Predicate Device (Primary)
Image Assessment Rendering	- Volume rendering, MIP, MPR, MinIP, Raysum (ThickMPR) - 3D triangulation - Perspective endoluminal view - Medial Axial Reformat (MAR) - Curved Planar Reformat (CPR) - Double-oblique MIP and MPR - Image enhancement filters - Synchronized side-by-side viewing - Synchronized center of rotation viewing - Cube View - Workflow templates - Multi-Mask Display (multi- object display) - User-defined measurement protocols - Editing tools: crop, cut, free- hand	- Volume rendering, - MIP, MPR, MinIP, - Raysum (ThickMPR) - 3D triangulation - Perspective endoluminal view - Medial Axial Reformat (MAR) - Curved Planar Reformat (CPR) - Double-oblique MIP and MPR - Image enhancement filters - Synchronized side-by- side viewing - Synchronized center of rotation viewing - Cube View - Workflow templates - Multi-Mask Display (multi-object display) - User-defined measurement protocols - Editing tools: crop, cut, free-hand	- Orthogonal, oblique, double oblique, curved, cross-curved, stretched - MPR rendering - MIP, AveIP, MinIP and color volume slabs - MIP volume rendering - Color volume rendering - Grayscale volume rendering - 2D slice review and stack comparison - 4D cine - Interactive VOI clipping - Multi-tissue color and opacity control - Active presets - User-defined presets
Storage of Results	- Structured reporting with xml, text, xls output - Word and html report - DICOM SC - Workflow scenes: restore saved state	- Structured reporting with xml, text, xls output - Word and html report - DICOM SC - Workflow scenes: restore saved state	- - Printout - Session state - PDF format - DICOM PDF report
Conferencing and Collaboration	Conferencing and Collaboration	Conferencing and Collaboration	N/A
Operating System	Microsoft Windows	Microsoft Windows	Microsoft Windows

Summary of Clinical Performance Tests:

iNtuition-Structural Heart Module did not require clinical studies to demonstrate its safety and effectiveness.

General Safety and Effectiveness Concerns:

iNtuition-Structural Heart Module doesn't present any safety concerns or effectiveness. iNtuition- Structural Heart Module has the same standard and part of optional features, technological characteristics, and similar indications for use than its predicates.

iNtuition-Structural Heart Module instructions for use are included within the device labeling provided in Volume 013 and in Appendix A, and the information provided in the labeling 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 from early design phase till design software validation and release. These potential hazards are controlled during software development by verification and validation testing. Furthermore, the software operators are healthcare professionals who are responsible for making all final patient management decisions.

Conformance Standards:
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 have been utilized in the production of the software.

The device complies with the following conformance standards:

- ISO 14971:2007- Medical devices - Application of risk management to medical devices.
- IEC 62304:2006/A1:2015 - Medical device software - Software life cycle processes.
- IEC 62366-1:2015 - Medical Devices - Application of usability engineering to medical devices.
- NEMA PS 3.1-3.20 (2016) - Digital Imaging and Communications in Medicine (DICOM) set.

Performance Data
The verification and Validation tests have been performed to address the indication for use, the technological characteristics claims, requirement specifications and risk management results.

Substantial Equivalence:
In all material aspects, iNtuition-Structural Heart Module 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 being formalized and after ensuring that the software fully satisfies all expected and previously defined system requirements and features. Test results support the conclusion that iNtuition- Structural Heart Module performance satisfies the design intent and is equivalent to its predicate devices.

Conclusion:

iNtuition-Structural Heart Module, as described in this premarket notification, has similar indication for use and same technical characteristics as the predicate devices, and therefore, is substantially equivalent in terms of basic design, features and intended use to those predicates.

In summary, TeraRecon, Inc., believes that iNtuition-Structural Heart Module is an optional feature of iNtuition (K121916) and doesn't present any new safety or effectiveness risks to users and is substantially equivalent to and performs as well as the predicate devices.