



K121916

APR 02 2013

Date of Summary: 1st April, 2013

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

iNtuition

Submitter/: TeraRecon Inc.
Applicant/ 4000 E 3rd Ave, Suite 200
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Establishment: 2954793
Registration #

Device Information:

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

Aquarius Workstation (K011142),
AquariusNET Server (K012086)
AquariusAPS Server (K061214)
VitreaView (K122136),
IQQA-Liver Software (K061696)

Indications for Use:

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 centerlines, which may be used to analyze cross-sections of structures, or to provide flythrough visualizations rendered along such a centerline. 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.

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.

Device Description:

iNtuition 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 described elsewhere in this document. The system 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 (with conference capabilities). iNtuition supports the physician in medical image viewing.

A fully-configured iNtuition system is capable of various image processing and visualization functions, including full-color Volume Rendering, Calcium Scoring, Segmentation Analysis and Tracking (SAT), Vessel Analysis, Flythrough, Multi-phase review, CT/ CTA Subtraction, Lobular Decomposition (LD), iGENTLE, Maxillo-Facial, Volumetric Histogram, Findings Workflow, Fusion CT/ MR/ PET/ SPECT, MultiKV etc. Each of these features may be offered as an independent upgrade option to the basic configuration.

The intended use of the device is to provide solutions to various medical image analysis and viewing problems, which come about as modalities generate more and more images. It also supports image distribution over networks, and is DICOM compliant.

For example, modern CT scanners produce up to several hundred slices per second, which cannot easily be scrutinized one by one. Although the iNtuition software offers this one-by-one viewing capability, it also is capable, when appropriate, of combining many slices to generate a volume-rendered view of the data. Modern MRI, PET and other scanners or imaging devices pose the same problem to the medical imaging professional.

Volume rendering, i.e. the computation of a three-dimensional object and its visualization in semi-transparent style on a screen, also includes segmentation of the volume into multiple irregular volumes of interest, which enhances recognition and analysis of otherwise hidden or overlapping features.

Another use is taking advantage of the 3D/2D-display option, in which the 3D view can be used to identify a location of interest which is then cross-referenced to the two-dimensional cross-section view(s).

Statistical analysis such as a histogram representation of the image density values in an image is supported. Advanced navigation tools for centerline-extracted flight paths and flythrough of any air or dye contrasted structure including, for example, the colon, vessels, or pulmonary airways are supported. When appropriate, the system can generate a sequence of 3D images, adding a 4th dimension of time, and hence providing a 4D analysis capability. Image analysis support for endovascular procedures such as analysis of images of thrombus, calcifications, and endoleaks can be carried out using the iNtuition tools. To study changes in user identified lesion volume and to track growth or shrinkage over time; for example, to analyze and track the progression/regression of tumors identified by the physician, the Segmentation, Analysis and Tracking (SAT) tool is provided. Calcium Scoring based upon established algorithms is possible, for the non-invasive detection and quantification of atherosclerotic plaque. Finally, iNtuition offers 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.

The software also facilitates executing any of the above functions on a remote viewer on defined and appropriately secured networks.

Technological Characteristics:

iNtuition will be marketed as a software only solution for the end-user (with recommended hardware requirements) or as a complete workstation for the end user (software package with hardware kit).

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 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, did not require clinical studies to show safety and effectiveness of the software.

General Safety and Effectiveness Concerns:

The introduction of iNtuition has no significant concerns of safety and efficacy. iNtuition in comparison with its predicate devices is a collectively enhanced solution which has 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 as described in this premarket notification has 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 is a collectively enhanced solution which does not include any new potential safety or effectiveness risks and is substantially equivalent to and performs as well as the predicate devices.



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

April 2, 2013

Robert Taylor
President
TeraRecon
4000 East 3rd Avenue, Suite 200
FOSTER CITY CA 94404

Re: K121916
Trade/Device Name: iNtuition
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: LLZ
Dated: April 1, 2013
Received: April 1, 2013

Dear Dr. Taylor:

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 go to <http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. 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

510(k) Number (if known): K121916

Device Name: iNtuition

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Prescription Use

(Part 21 CFR 801 Subpart D)

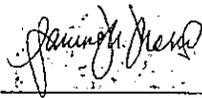
AND/OR

Over-The-Counter Use

(21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of *In Vitro* Diagnostics and Radiological Health (OIR)



(Division Sign Off)

Division of Radiological Health
Office of In Vitro Diagnostics and Radiological Health