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510(k) Premarket Notification
Summary of Safety and Effectiveness Information

AquariusAPS Server
December 16, 2005

Trade Name: *AquariusAPS Server*
Common/Usual Name: Server for image processing and communication
Classification Name: System, Image Processing

MAY 15 2006

Establishment Name and Registration Number:
Name: TeraRecon, Inc.
Number: 2954793

Classification:
21 CFR § 892.2050, Picture Archiving and Communications System, Class II, proposed exempt, final rule pending.

ProCode: 90-LLZ

Equivalent Device(s):
1. *Aquarius Workstation*-K011142 by TeraRecon Inc.
2. *AquariusNET Server*- K012086 by TeraRecon Inc.
3. *Lung CAR*-K041807 by Medicsight PLC.
4. *Colon CAR*-K042674 by Medicsight PLC.
5. *Fusion 7D*-K020546 by Mirada Solutions, Ltd.

Parts of these devices are substantially equivalent in terms of basic design, features and intended use.

Applicant/Sponsor Name/Address:
TeraRecon Inc.
2955 Campus Drive, Suite 325
San Mateo, CA 94403
Tel: (650) 372-1100
FAX: 650-372.1101

Contact Person:
Emilly Tojima
Quality Assurance and Regulatory Affairs Manager
TeraRecon Inc.
2955 Campus Drive, Suite 325
San Mateo, CA 94403
Tel: (650) 372-1100

Description of the Device:
The AquariusAPS server receives medical images from medical imaging acquisition devices adhering to the DICOM protocol for image transfer such as EBT, CT, MRI, and other volumetric or planar medical imaging modalities, and performs digital image processing to derive certain information or new images from these image sets. The information or new images thus derived is transmitted using the DICOM protocol to other devices supporting this standard protocol. Lossy compressed mammographic images and digitized film screen images must not be reviewed for primary image interpretations. Mammographic images may only be interpreted using an FDA approved monitor that offers at least 5 Mpixel resolution and meets other technical specifications reviewed and accepted by FDA."

The intended use of the device is to provide time-saving pre-processing of images to remove the need for an image review system to perform these activities while a user is waiting for processing to complete, to optimize the use of the user's time.

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Hardware & Software Information

The AquariusAPS Server utilizes standard "off the shelf" personal computer systems as its hardware platform. The software requires the use of the Windows NT 4.0 or Windows 2000 operating system, and a Pentium III – class processor or equivalent.

The software designed to control and manipulate the diagnostic images are based upon information and guidance found in the list of standards provided in Appendix III. In accordance with TeraRecon's software development procedures, the level of concern relative to this software has been determined through information obtained from the FDA Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices (2005).

Feature Comparison Table

Feature	Aquarius APS	Aquarius NET Server	Aquarius Workstation	Lung CAR Medicsight	Colon CAR Medicsight	Fusion 7D Mirada Solutions
2D, 3D Image Review	No	Yes	Yes	No	No	No
Removal of the CT table from a CT examination	Yes	Yes	Yes	No	No	No
Removal of bony structures from a CT examination	Yes	Yes	Yes	No	No	No
Calculation of a centerline through a hollow organ or structure, or vessels, for a CT or MR scan	Yes	Yes	Yes	No	No	No
Isolation of tissue in the vicinity of and including the heart from a CT scan	Yes	No	Yes	No	No	No
Calculation of a parametric color overlay map for time-dependent a MR or CT scan	Yes	No	Yes	No	No	No
Identifying locations of sphere-like structures in a CT scan	Yes	No	Yes (Manual)	Yes	Yes	No
Calculation of a set of images in certain orientations or planes using MPR, MIP, VR or other rending techniques.	Yes	Yes	Yes	No	No	No
Calculation of a transformation to register one set of images to another	Yes	Yes (Manual)	No	No	No	Yes
Calculation of the volume of a certain structure, possibly with time dependence	Yes	No	Yes	No	No	No
Receiving images using DICOM transfer protocols	Yes	Yes	Yes	Yes	Yes	Yes
Sending Images and other data using DICOM transfer protocols	Yes	Yes	Yes	Yes	Yes	Yes
Performing actions based on DICOM tags contained in images received by DICOM	Yes	Yes	No	No	No	No
Administration control through a browser-based interface	Yes	Yes	No	No	No	No
Export of images and image sequences in a variety of formats	Yes	Yes	Yes	Yes	Yes	Yes

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
9200 Corporate Blvd.
Rockville MD 20850

MAY 15 2006

TeraRecon, Inc.
% Mr. Daniel W. Lehtonen
Responsible Third Party Official
Intertek Testing Services NA, Inc.
2307 East Aurora Rd., Unit B7
TWINSBURG OH 44087

Re: K061214
Trade/Device Name: AquariusAPS Server
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: LLZ
Dated: May 1, 2006
Received: May 2, 2006

Dear Mr. Lehtonen:

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.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such 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); 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.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

21 CFR 876.xxxx	(Gastroenterology/Renal/Urology)	240-276-0115
21 CFR 884.xxxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 892.xxxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). 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) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html

Sincerely yours,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

510(k) NUMBER (IF KNOWN): K061214

DEVICE NAME: AquariusAPS

INDICATIONS FOR USE:

The AquariusAPS server receives medical images from medical imaging acquisition devices adhering to the DICOM protocol for image transfer such as EBT, CT, MRI, and other volumetric or planar medical imaging modalities, and performs digital image processing to derive certain information or new images from these image sets. The information or new images thus derived is transmitted using the DICOM protocol to other devices supporting this standard protocol.

Lossy compressed mammographic images and digitized film screen images must not be reviewed for primary image interpretations. Mammographic images may only be interpreted using an FDA approved monitor that offers at least 5 Mpixel resolution and meets other technical specifications reviewed and accepted by FDA.

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 CDRH, Office of Device Evaluation (ODE)

Nancy C Brogdon

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K061214