SEP 1 3 2001 K012086

510(k) Premarket Notification Summary of Safety and Effectiveness Information	***AquariusNET Server*** ***June 26, 2001***

Trade Name: *Aquarius*NET *Server*

Common Name: Image communication and storage system

Classification Name: System, Digital Image Communication, Teleradiology System

Establishment Name & Registration Number:
Name: TeraRecon, Inc.
Number: Pending

Classification:
§ 892.2020, System, Image Processing. Class I, proposed exempt, final rule pending.

§ 892.2050, Picture Archiving and Communication System. Class I, proposed exempt, final rule pending.

ProCode(s): 90-LLZ & 90-LMD

Equivalent Device(s):
1. Imatron Ultra Access Workstation with Cardiac Software Extensions (K972903).

2. *IiVS™ Integrated image Viewing Station* (K994329).

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

Description of the Device:
*Aquarius*NET is a device consisting of a DICOM server that receives and stores images from a PACS or other image giving modalities. It archives images in a scalable storage medium and delivers them in response to DICOM Query/Retrieve requests from other DICOM devices on the network (not part of *Aquarius*NET). It also serves image requests to its remote "thin clients", which act as the graphical user interface to the *Aquarius*NET server. The server can host multiple concurrent sessions from remote "thin clients". *Aquarius*NET features an integrated 2D/3D streaming engine which allows regular PCs or notebooks to control the server, and to review 2D images and 3D reconstructions interactively over a network. *Aquarius*NET is capable of image review, communications, archiving, database maintenance, reporting and basic 3D capabilities described elsewhere in this document. It is also capable of full-color Volume Rendering and Calcium Scoring.

Applicant/Sponsor Name / Address:
TeraRecon, Inc.
2955 Campus Drive, Suite 325,
San Mateo, CA 94403
650.372.2668

Contact Person:
Mr. Robert Taylor
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TeraRecon Inc.,
2955 Campus Drive, Suite 325, San Mateo, CA 94403
650.372.2668

Submission Correspondent:
Mr. David W. Schlerf
Buckman Company, Inc.
200 Gregory Lane, Suite C-100
Pleasant Hill, CA 94523-3389
925.356.2640 / 925.356.2854 FAX

Hardware & Software Information:
The *Aquarius*NET Server utilizes standard "off the shelf" personal computer systems as its hardware platform. The software requires the use of 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 follows the international standard ISO/IEC 12207: 1995 Information Technology - Software Life Cycle Processes. In accordance with that standard, the level of concern relative to this software has been determined using the decision tree provided in Version 1 of the FDA Software Guidance.

Feature Comparison Table:

Feature	***Aquarius*NET Server**	**Imatron Ultra Access 972903**	**TeraRecon IiVS K994329**
2D Image Review	Yes	Yes	Yes
Multiplanar reformatting	Yes	Yes	Yes
3D Volume Rendering	Yes	Yes	Yes
Maximum Intensity Projection	Yes	Yes	Yes
Image Archiving	Yes	Yes	Yes
Image Filming	Yes	Yes	Yes
Image Transfer or Network Connectivity	Yes	Yes	Yes
Examination of 2D image data from a calcium scan	Yes	Yes	Yes
Examination of calcium scan as a 3D volume	Yes	Yes	Yes
Semi-automated identification of regions that are considered calcium	Yes	Yes	No
User override of automatically identified regions	Yes	Yes	No
Automatic calculation of calcium score	Yes	Yes	No
Ability to measure CT numbers on a 2D image	Yes	Yes	Yes
Saving of calcium data with patient exam data	Yes	Yes	No
Creation of a paper calcium report	Yes	Yes	No
Comparison of multiple scans	Yes	Yes	Yes
Indications for use – general medical imaging workstations	Yes	Yes	Yes
Indications for use – calcium	Yes	Yes	No

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 1 3 2001

TeraRecon, Inc.
% Mr. David W. Schlerf
Buckman Company, Inc.
200 Gregory Lane, Suite C-100
PLEASANT HILL CA 94523-3389

Re: K012086
Trade/Device Name: AguariusNET Server
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture Archiving and Communications System
Regulatory Class: II
Product Code: 90 LLZ
Dated: June 26, 2001
Received: July 3, 2001

Dear Mr. Schlerf:

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 (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); 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 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:

8xx.1xxx	(301) 594-4591
876.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4616
884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx	(301) 594-4616
892.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4654
Other	(301) 594-4692

Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained 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/dsma/dsmamain.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: K012086

DEVICE NAME : ***Aquarius*NET Server**

INDICATIONS FOR USE:

The *Aquarius*NET Server acquires, stores, transmits, and enables compatible computers on a network to display medical images from medical scanning devices such as EBT, CT or MRI and patient reports of various types. Teleradiology, image acquisition, distribution, archiving, image manipulation, 3D and 4D visualization are supported. Calcium scoring from whole body computed tomography derived measurements, for non-invasive detection and quantification of atherosclerotic plaque. Tools for histogram analysis of the density distribution of certain regions of interest are provided. A database management and report generation tool is included.

PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NECESSARY

Concurrence of CDRH, Office of Device Evaluation (ODE)

Nancy C Brogdon

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K012086

Prescription Use ✓ OR **Over-The-Counter Use** _____
(Per 21 CFR 801.109) (Optional format 1-2-96)