

MAY 26 2000

K994329
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510(k) Premarket Notification
Summary of Safety and Effectiveness Information

***DiVS & IiVS™ Integrated
image Viewing Stations***

Device Name:

Trade Name: ***DiVS & IiVS™ Integrated image Viewing Stations***
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:

Title 21, Code of Federal Regulations, § 892.2020 & § 892.2050. Now proposed exempt, final rule pending.
ProCode: 90-LMD & 90-LLZ

Equivalent Device(s):

Acculmage™ Viewer Products, K961023, by Acculmage, Inc.
The referenced systems are equivalent to the *DiVS and IiVS™ Integrated image Viewing Stations* in terms of basic design, features and intended use.

Description of the Device:

The *IiVS™ Integrated image Viewing Station* is a product family, which comes in two different versions:

DiVS: a DICOM viewer
IiVS: a 3D viewer

The intended use of the devices is to provide solutions to various medical image-viewing problems, which come about as the modalities generate more and more images. They also support image distribution over networks, and are DICOM conformant.

Finally, the *IiVS™ Integrated image Viewing Station* family supports the radiologist in writing a report, and transmitting and storing this report in digital form.

Applicant / Sponsor Name / Address:

TERARECON, INC.
2955 Campus Drive, Suite 325
San Mateo, CA 94403
650.372.2669

Contact Person:

Horst Brüning, Ph.D.
VP Engineering
TERARECON, INC.
2955 Campus Drive, Suite 325
San Mateo, CA 94403
650.372.2669

Submission Correspondent:

Mr. David W. Schlerf
Buckman Company, Inc.
200 Gregory Lane, Suite C-100
Pleasant Hill, CA 94523-3389
925.356.2640 / 925.356.2654 FAX

Manufacturing Facility:

At the present time, the *DiVS & IiVS™ Integrated image Viewing Station* is manufactured by TeraRecon, Inc.

Performance Standards:

There are no applicable FDA mandated performance standards for this device. However, voluntary standards such as DICOM, various in-house Standard Operating Procedures and vendor qualification procedures are in place and utilized in the production of the software.

The software designed to control and manipulate the diagnostic images follows the international standard ISO/IEC 12207: 1995 Informatin 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.

Hardware requirements

The DiVS will execute on Silicon Graphics SGI-320 and 540 workstations under Windows NT4.0. Memory requirements are 640 MB.

User interface

The user interacts with the system through a standard keyboard and a wheel-mouse. All buttons are marked with commonly understood symbols or English language notation.

Data input:

DTCOM file transfer:
Compliance with DICOM 3 Query and Retrieve
Max. file size: 512 MB or 1000 slices

Video Input:

NTSC video input signals at 30 frames per second.

Data output:

Data output is user defined and is one of 3 options:

1. DICOM file
2. JPEG compressed image file
3. BMP file

Video output:

NTSC-compatible video output as an option.

The Report Function

Provide preset image format for included images. This format has to be easily modified. Overlay of figures and characters on top of the images to annotate findings. Provide for placing the report on a network as DICOM files or BMP or JPEG format. Provide a print function.

Hardware Information:

The IiVS will execute on Silicon Graphics Visual Workstations VW 320 or VW 540. The following configuration is used:

VW 320

Silicon Graphics 320 Base Model
 Dual Pentium III 500 MHz
 640 MB of SDRAM
 14.4 GB hard disc
 32x CD-ROM
 Silicon Graphics 1600 SW flat panel monitor
 MS IntelliMouse with wheel
 USB keyboard

VW 540

Silicon Graphics 540 Base Model
 Quad Pentium III Xeon 550 MHz
 640 MB of SDRAM
 9.1 GB Ultra 2 SCSI hard disc
 e.-h. same as model 320

Comparison Table:

FEATURE	<i>DIVS & IIVS™</i>	<i>Acculmage™</i>	SE ?
Intended Use:	Teleradiology image acquisition, distribution, archival and 3D viewing.	SAME	Yes
Network Connectivity:	Ethernet 100 Base T	General Purpose Interface Protocol - GPIB IEEE488	Yes
Computer Platform:	SGI VW-320 and -540	PC	Yes
Lossy Image Compression:	JPEG	BMP	Yes
DICOM Compliant:	YES	YES	Yes
Image Display:	Color, Grey scale, 1600x1200	Color, Grey scale, 512x512	Yes
Image Edit:	8 object segmentation clipping planes in double oblique orientation	Manual and threshold segmentation	Yes
Volume Rendering:	Voxel transmission, parallel and perspective ray casting	MIP, Surface rendering, Depth encoded surface,	Yes
2D/3D Integration:	Automatic display of orthogonal planes	Display of basic 2D views	Yes
Operating System:	SGI320 , SGI-540 Windows NT	Win95/Win98	Yes



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 26 2000

Terarecon, Inc.
c/o David W. Schlerf
Buckman Company, Inc.
200 Gregory Lane
Suite C-100
Pleasant Hill, CA 94523

Re: K994329
iiVS™ Integrated Image Viewing Station
Dated: April 14, 2000
Received: May 1, 2000
Regulatory class: II
21 CFR 892.2050/Procode: 90 LMD/90 LLZ

Dear Mr. Schlerf:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we 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). 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 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

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 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4591. 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" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers 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,

Daniel G. Schultz, M.D.
Captain, USPHS
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure(s)

510(k) Number (if known): K994329

Device Name: ***IiVS™ Integrated image Viewing Station***

Indications For Use:

Acquire, store, transmit, and display medical images and patient reports of various types. Teleradiology image acquisition, distribution, archive and viewing.

PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NECESSARY
Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use
(Per 21 CFR 801.109)

OR

Over-The-Counter Use
(Optional format 1-2-96)

David A. Seymour
(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K994329