K022938

510(K) Summary

The following safety and effectiveness summary has been prepared pursuant to requirement for 510(K) summaries specified in 21CFR 807.92(a)

Submitter Information

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Contact Person

John Baby, Process Development Manager, QA/RA

Date Prepared

August 26, 2002

Device Name

Trade Name

Dextroscope™, DextroBeam™, VizDexter™ 2.0

Common Name

Image Processing System

Classification Name

Picture Archiving and Communications System (per 21 CFR 892.2050)

Classification Number

LLZ

Devices to which substantial equivalence is being claimed

The Volume Interactions Image Processing System is substantially equivalent to

510(k) Number	Device Name	Manufacturer
K992654	Plug n View 3D, Version 1.0	Voxar Limited
K002519	Vitrea 2, Version 2.1	Vital Images Inc.

Device Description

Volume Interactions Image Processing System reads DICOM 3.0 format medical image data sets (and other formats) and displays 3D image reconstructions of these data sets through various user selectable industry standard rendering methods and algorithms. The clinical users can spatially manipulate, process to highlight structures and volumes of interest, and measure distances and volumes in the 3D image reconstructions. The processed data can be

stored either as 3D image data in a proprietary format, or as 2D picture projections of the 3D image data in TIFF image format. The system runs on commercially available IBM PC compatible computers and hardware components with the Microsoft Windows NT and 2000 operating systems.

The system consists of three product modules namely, VizDexter™ 2.0, Dextroscope™ and DextroBeam™. The modules are described as follows:

VizDexter™ 2.0 is software that processes tomographic (e.g.: Computer Tomography, Magnetic Resonance Imaging) data and produces stereoscopic 3D renderings for surgery planning and visualization purposes. The software uses various user selectable industry standard rendering methods and algorithms.

Dextroscope™ is an interactive console and display system that allows the user to interact with two hands with the 3D images generated by the VizDexter™ software. The Dextroscope™ user works seated, with both forearms positioned on armrests. Wearing stereoscopic glasses, the user looks into a mirror and perceives the virtual image within comfortable reach of both hands for precise hand-eye coordinated manipulation. The hardware uses various industry standard components.

DextroBeam™ is an interactive console intended for group collaborative discussions with 3D images using a stereoscopic projection system. The DextroBeam™ system uses the base of the Dextroscope™ as the 3D interaction interface with the virtual objects. The monitor of the Dextroscope™ is replaced by a screen projection system, so instead of looking into the mirror of the Dextroscope™, the user looks at large stereoscopic screen projections while working with the virtual data in reach of his hands. This enables the discussion of 3D data sets with other specialists in stereoscopic 3D. The hardware uses various industry standard components.

Intended Use

Volume Interactions Pte Ltd's Image Processing System is a medical device for the display and 3D visualization of medical image data derived from CT and MRI scans. It is intended to be used by qualified and trained medial professionals, after proper installation.

Volume Interactions Pte Ltd's Image Processing System is not intended to be used in direct contact with the patient nor is it intended to be connected to equipment that is used in direct contact with the patient

Comparison of Technological Characteristics

The Volume Interactions Image Processing System is substantially equivalent to Voxar Limited Plug n View 3D, Version 1.0 (K992654) for non measurement features and Vital Images Vitrea 2, Version 2.1 (K002519) for measurements.

Feature	Volume Interactions Image Processing System (VizDexter™ 2.0, Dextroscope™, DextroBeam™)	Voxar Plug n View 3D, version 1.0
510(k) number		K992654
Intended use	Intended for the display and 3D visualization of medical image data derived from CT and MRI scans. It is intended to be used by qualified and trained medial professionals, after proper installation.	Intended for use by radiologists, clinicians and referring physicians to acquire, process, render, review, store, print and distribute DICOM 3.0 complaint image studies, utilizing standard PC

		hardware.
Type of software Program	Stand alone application program	Stand alone application program
Software platform used	Windows NT, Windows 2000 professional	Windows 95/98/NT
Stereoscopic Interactive console	Dextroscope or DextroBeam	None
Communications	TCP/IP	TCP/IP
Image Format In	DICOM 3.0, Classic SGI, TIFF, RAW	ACR NEMA 2.0, DICOM 3.0
Image Format out	TIFF image format	DICOM 3.0
Image Display	Color CRT or Stereoscopic Projection System	Color/Grayscale, CRT or Laptop LCD
Image Archive	SCSI 10-30 Gbytes, CD-ROM	SCSI 2-20 Gbytes, CD ROM
Printing	No	Printing to standards window printers
Prescriptive Device	Prescription use only	Prescription use only
Segmentation by Threshold selection	Yes	Yes (Window level Presets)
Morphology Segmentation Manager	Yes	Yes (Limited)
Segmentation by Contour Editor	Yes	Yes (Shape & Sculpt)
Volume Rendering, Triplanar Mode and 3D view		
Simultaneous display of coronal + saggital + axial plane	Yes (Triplanar Mode)	Yes (Multi Planar Reformatting (MPR) view)
Translate 3 Planes	Yes	Yes
Display lines of intersection between planes	Yes (shown as actual 3D plane intersections)	No
Patient orientation Labels	No	Yes
Patient Labels	Yes	Yes
Adjustable text on labels	Yes	Yes
Borders to highlight "current" plane	Yes	Yes
Reset pan/zoom/orientation	Yes	Yes

Show Volume Rendering and Triplanar view concurrently	Yes	Yes (shows Volume Rendering and 3 quadrant views)
Adjustable clipping in Triplanar Mode	Yes	Yes (in 3 quadrant views)
Volume Rendered 3D Display mode	Yes	Yes
Polygonal Surface object display mode	Yes	No
Multi-modality Volume Rendered Display mode	Yes	No
MIP Display Mode	No	Yes
Basic Tools		
Volume	Yes	Yes
Crop	Yes	Yes (Shape tool)
Cut	Yes	No (only orthogonal cuts)
Pick	Yes	Yes (Selection tool)
Zoom	Yes	Yes
Pitch	Yes	Yes (resolution varies during image movement)
View Box	Yes	Unknown
Color and transparency editing	Yes (Volume Console)	Yes (Active Color Presets)
Image Processing		
Rotation	Yes	Yes
Pan	Yes	Yes
Zoom	Yes	Yes
Flip according to patient orientation	Yes (Manual Flipping)	Yes
Opacity	Yes	Yes
Orthogonal clipping	Yes	Yes
Sculpting	Yes (Contour Editor)	Yes (Shape & Sculpt tool)
Window level protocols	No	Yes
Image Layout		
Show Single Screen	Yes	Yes
Show four quadrants view (coronal + saggital + axial+ 3D)	No	Yes

Multi-modal volume rendering		
3D registration	Yes	No
Multimodal fusion of CT and MR scans	Yes	No
Image Storage		
Add captured 3D rendered image to user profiles	Yes (as TIFF files)	Yes
Record movie clips	Yes	Yes
Hardcopy generation		
Print to DICOM and NON-DICOM printers	No	Yes
Image Editing Tools	Erase and Restore	Tools for removal of obscuring anatomy
Measurements		
Distance	Yes	Yes
Area	No	No
Volume	Yes	Yes

Feature	Volume Interactions Image Processing System (VizDexter ™ 2.0, Dextroscope ™, DextroBeam ™)	Vital Images Vitrea 2, Version 2.1
510(k) number		K002519
Intended use	Intended for the display and 3D visualization of medical image data derived from CT and MRI scans. It is intended to be used by qualified and trained medial professionals, after proper installation.	Intended for processing / analyzing 2D/3D images from CT / MR scanners.
Type of software program	Stand alone application program	Stand alone application program
Software platform required	Windows NT, Windows 2000 professional	Windows NT
Stereoscopic Interactive console	Dextroscope or DextroBeam	None
Medical Image Modalities		
All DICOM 3.0 recognized modalities where datasets are comprised of parallel, 2D images with know inter-image spacing	Yes	Yes
Measurements		
Distance	Yes	Yes
Area	No	Yes
Volume	Yes	Yes
Interactive contour definition of lesions	Yes (Contour Editor)	No
Safety: Clinician review/editing of data	Yes (distance and volume measurements are displayed, can be modified and be accepted or rejected by clinician)	Yes (clinician interactive reviews and edits the data)
Data Source	CT/MR scanners	CT/MR scanners
Stereoscopic view	Yes	No
Dextroscope Technology (direct hand access of 3D objects using 3D joystick and 3D stylus)	Yes	No

Discussion of similarities and differences

The software module VizDexter™ 2.0 of the Volume Interactions Image Processing System utilizes similar technological characteristics as the predicate devices. All provide multi-view user interfaces with combinations of 2D and 3D views correlated together for enhanced visualization. All provide measurement tools for analysis of the observed structures (volumes); and allow virtual lighting parameters to emphasize details.

VizDexter™ 2.0 and all predicates, provide 3D views. As with Vitrea 2 and Voxar Plug n View 3D, VizDexter 2.0 utilizes direct volume rendering for all its 3D views, including transparent volume images and visible surface views. For changing the mapping to opacity during translucent views, VizDexter 2.0 is similar to Voxar Plug n View 3D and Vitrea 2.

VizDexter™ 2.0 has functions of multi-modal volume rendering and a registration facility, which are not present in Plug n View 3D and Vitrea 2.

Volume Interactions Image Processing System and all predicates use identical technology to manipulate and display the 2D image views of the data sets (industry standard mouse and keyboard and a computer monitor). VizDexter™ 2.0 differs from all predicates however in the user interface utilized to manipulate the 3D image data, and in the display of the 3D image data. The user interfaces of the Dextroscope and the DextroBeam utilize an industry standard 3D tracker to position and orient the 3D image data with both hands, for ease of manipulation. The display of the 3D data is achieved by wearing stereoscopic glasses to view the 3D images of a computer monitor through a normal mirror (Dextroscope ™) or to view the 3D images displayed by a stereoscopic projector (DextroBeam ™). Voxar Plug n View 3D and Vital Images Vitrea 2.0 do not provide stereoscopic display nor hand controlled 3D trackers and follow the conventional keyboard and mouse interface for 2D and 3D interactions.

Technological characteristics

The device does not contact the patient, nor does it control any life sustaining devices. A physician providing ample opportunity for competent human intervention, interprets images and information being displayed.

Conclusion

We conclude that the Volume Interactions Image Processing System (VizDexter™ 2.0, Dextroscope ™ and DextroBeam ™) is substantially equivalent to its predicate devices in its ability to render 3D images for use in medical analysis. In comparison of the predicate devices Volume Interactions Image Procession System provides a user interface that utilizes both hands to manipulate the 3D image data, and a stereoscopic display to view the 3D image data, which the predicate devices do not provide.

Regarding safety and effectiveness, Volume Interactions Pte Ltd is an ISO 9001:2000 certified company. All processes are controlled and monitored. Risk management including risk analysis, verification and validation tests, and evaluation by hospitals control potential hazards in both software and hardware. The level of concern for the Volume Interactions Image Processing System is minor.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 25 2002

Mr. John Baby
Process Development Manager
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5 Shenton Way
#37-04 UIC Building
068808 SINGAPORE

Re: K022938
Trade/Device Name: VizDexter Version 2.0;
Dextroscope MK8; Dextrobeam MK3
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and
communications system
Regulatory Class: II
Product Code: 90 LLZ
Dated: August 30, 2002
Received: September 4, 2002

Dear Mr. Baby:

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

2. Indications for Use

510(k) Number: K022938

Device Name: Image Processing System

Indications for Use:

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over The Counter _____

(Per 21 CFR 801.109)

(Optional Format 1-2-96)

David A. Seymour

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K022938