K071054

510(k) Summary Of Safety and Effectiveness

MAY 22 2007

RadioDexter™, Dextroscope™ and Dextrobeam™

Submitter Information

Manufacturer:	Volume Interactions Pte Ltd 1 Kim Seng Promenade #12-01 Great World City East Tower Singapore 237994 Phone: + 65 62226962 ext 232 Facsimile: + 65 62226215
Contact Person:	Michael Sim, Director, Worldwide Operations
Summary Date:	9th April 2007

Device Name

Common Name:	Image Processing System
Trade Name: & Model No.	RadioDexter™ 1.0, Dextroscope™ MK10, Dextrobeam™ MK3 & MK4
Classification Name:	Picture Archiving and Communications System (per 21 CFR 892.2050)
Classification Number:	LLZ

Intended Use

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

Predicate device

Trade Name & Model No.:	RadioDexter™ 1.0, Dextroscope™ MK10, Dextrobeam™ MK3 & MK4
510(K) number:	K063730

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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 PC compatible computers and hardware components with the Microsoft Windows NT and 2000 operating systems.

The system consists of three product modules namely, RadioDexter™, Dextroscope™ and Dextrobeam™. The modules are described as follows:

RadioDexter™ 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.

DTI (Diffusion Tensor Imaging)

DTI (Diffusion Tensor Imaging) is an add-on module to RadioDexter™. This module allows the user to visualize white matter anatomy in the form of fiber tracks. The intended use of this module is to generate and provide a visual reference of white matter fiber tracks in a 3D virtual reality environment during the process of neurosurgery planning using the Dextroscope™ or during a discussion/collaboration using the Dextrobeam™. It is not intended to be used otherwise.

Dextroscope™ is an interactive console and display system that allows the user to interact with two hands with the 3D images generated by the RadioDexter™ 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.

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Substantial Equivalence

The Image Processing System in this submission remains unchanged as previously received 510(k)063730, in the following aspects:

- Use the same operating principle
- Have the same technological characteristics
- Incorporate similar basic software and hardware design
- Have the same fundamental scientific technology

The only differences are as follows:

Intended Use

The following statement has been removed from the intended use:
"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."

The device's input is derived from tomographic radiology images and the data format of the input is in either DICOM 3.0 or other common imaging formats (classic SGI formats, TIFF, Raw volume chunk or slices). It is clear that the input is not derived from patients directly which is why our company finds it redundant to highlight that there is no direct patient contact and connection to equipment that is used in direct contact with the patient. Removal of the statement does not affect the safety and effectiveness of the device as this does not change the system in terms of performance, design and technological characteristics.

DTI (Diffusion Tensor Imaging)

DTI (Diffusion Tensor Imaging) is an add-on module to RadioDexter™. This module allows the user to visualize white matter anatomy in the form of fiber tracks. The intended use of this module is to generate and provide a visual reference of white matter fiber tracks in a 3D virtual reality environment during the process of neurosurgery planning using the Dextroscope™ or during a discussion/collaboration using the Dextrobeam™. It is not intended to be used otherwise.

DTI has been verified and validated according to Volume Interactions' procedures for product design and development. The validation proves the safety and effectiveness of the module.

Conclusion

In summary, the Image Processing System (Dextroscope™, Dextrobeam™ with RadioDexter™) described in this submission are, in our opinion, substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
9200 Corporate Blvd.
Rockville MD 20850

Mr. Michael Sim
Director, Worldwide Operations
Volume Interactions Pte Ltd
1 Kim Seng Promenade #12-01
Great World City East Tower
SINGAPORE 237994

MAY 22 2007

Re: K071054
Trade/Device Name: Image Processing System (Dextroscope™ MK10, Dextrobeam™ MK3 and MK4, and RadioDexter™ 1.0)
Regulation Number: 21 CFR §892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: LLZ
Dated: April 9, 2007
Received: April 16, 2007

Dear Mr. Sim:

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

INDICATION FOR USE STATEMENT

510(k) Number : K071054

Device Name : **Image Processing System (Dextroscope™ MK10, Dextrobeam™ MK3 and MK4, RadioDexter™ 1.0)**

Indication for Use

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

Prescription Use ✓ ~~AND~~/OR Over-The-Counter Use _____
(Per 21CFR 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 K071054