510(k) Summary of Safety and Effectiveness

K072653

This 510(k) summary of safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990.

Date Prepared: November 24, 2007

Submitter's Information: 21 CFR 807.92(a)(1)

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JAN 24 2008

Trade Name, Common Name and Classification: 21 CFR 807.92(a)(2)

Trade Name:	3viseon/surgery™
Common Name:	Picture Archiving Communications System
Device Classification:	892.2050 LLZ
Name:	System, Image Processing

Predicate Device: 21 CFR 807. 92(a)(3)

Device Classification Name	System, Image Processing, Radiology	System, Image Processing, Radiology
Regulation Number	892.2050	892.2050
510(k) Number	K060505	K043097
Device Name	VOXAR 3D ENTERPRISE, MODEL 6.1	3VISEON
Product Code	LLZ	LLZ
Decision	SUBSTANTIALLY EQUIVALENT (SE)	SUBSTANTIALLY EQUIVALENT (SE)
Classification Advisory Committee	Radiology	Radiology
Review Advisory Committee	Radiology	Radiology

Device Description: 21 CFR 807 92(a)(4)

3viseon/surgery™ is a software based application for picture archiving and communications system that provides users with capabilities relating to the acceptance, transfer, display, storage, and digital processing of medical images (including digital Mammograms). 3surgery is an advanced 2D and 3D visualization solution that enables surgeons to quickly and reliably prepare for various types of surgery, by combining 2D scan slices into comprehensive 3D models of the patient.

The software device should not be used during a surgical procedure.

3viseon/surgery™ works with all major medical image formats and can access multiple data stores, across networks or on CD-ROM / DVD. The software runs on any modern Windows based computer with a 3D graphics card that meets the minimum requirements, eliminating the need for specialized hardware.

510(k) Summary of Safety and Effectiveness

Indications for Use: 21 CFR 807 92(a)(5)

3viseon/surgery™ is a software device that receives digital images and data from various sources (i.e. CT scanners, MR scanners). Images and data are captured, stored, communicated, processed and displayed within the system and or across computer networks at distributed locations. Image tools are available such as 2D review, orthogonal Multi Planar Reconstructions (MPRs), oblique MPRs, curved/cross-curved MPRs, slab MPRs, AveIP, MIP, MinIP, vascular measurements, annotations, reporting, distribution, etc. Only DICOM, for presentation images will be captured for display and diagnosis. Analysis of images and diagnosis is not performed by the software but by physicians or trained professionals. Digitized film screen images must not be reviewed for primary image interpretation. Mammographic images must not be interpreted using this system.

Technological Characteristics: 21 CFR 807 92(a)(6)

3viseon/sugery™ is medical device image software that is used with computer hardware in a picture archiving and communications system user environment. 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 and printed.

Conclusion: 21 CFR 807 92(b)(1)

The 510(k) Pre-Market Notification 3viseon/sugery™ contains adequate information and data to enable FDA - CDRH to determine substantial equivalence to the predicate device.

3viseon/sugery™ will be manufactured in accordance with the voluntary standards listed in the enclosed voluntary standard survey. The submission contains the results of a hazard analysis and the "Level of Concern for potential hazards has been classified as "minor".

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 24 2008

3mensio Medical Imaging BV
c/o Carl Thomas, Consultant
OTech, Inc.
1600 Manchester Way
DENTON TX 76210

Re: K072653
Trade/Device Name: 3viseon/surgery™
Regulation Number: 21 CFR §892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: LLZ
Dated: January 13, 2008
Received: January 17, 2008

Dear Mr. Thomas:

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 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 Center for Devices and Radiological Health's (CDRH's) 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" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. 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 (240) 276-3150 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

(Indications for Use Form)

510(k) Number: K072653

Device Name: 3viseon/surgery™

Indications for Use:

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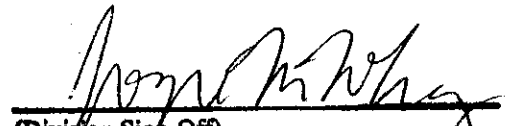
Mammographic images must not be interpreted using this system.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X AND/OR Over-The-Counter Use _____

(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)



(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K072653