K081093

MAY - 1 2008

510(k) Summary

Submitter's Name:	Eigen LLC
Submitter's Address:	13366 Grass Valley Avenue, Grass Valley, CA 95945
Submitter's Telephone:	530-274-1240
Contact Name:	Mark A. Hoffman
Date Summary was Prepared:	March 25, 2007
Trade or Proprietary Name:	3-D Imaging Workstation
Common or Usual Name:	Medical Image Processing Workstation
Classification Name:	System, Image Processing, Radiological, LLZ Picture Archiving and Communications, 21CFR 892.2050

Predicate Devices:

Device Name	510(k) Number
3-Dnet Suite	K063107
XELERIS 2 Processing and Review Workstation	K051673

Description of the Device and Summary of the Technological Characteristics

The 3-D Imaging Workstation is designed to display the 2-D live video received from commercially available ultrasound machines and use this 2-D video to reconstruct a 3-D ultrasound image. The system has been designed to work with the clinicians' existing ultrasound machine, end fire TRUS probe, commercially available needle guide and needle gun combination. Additional software features include patient data management, multi-planar reconstruction, segmentation, image measurement and 3-D image registration.

The 3-D Imaging Workstation is comprised of a mechanical assembly that holds the ultrasound probe and tracks probe position while the physician performs a normal ultrasound imaging procedure of the subject prostate. The mechanical tracker is connected to a PC-based workstation containing a video digitizing card and running the image processing software. Control of the ultrasound probe and ultrasound system is done manually by the physician, just as it would be in the absence of the 3-D Imaging Workstation. However, by tracking the position and orientation of the ultrasound probe while capturing the video image, the workstation is able to reconstruct and display a 3-D image and 3-D rendered surface model of the prostate.

The reconstructed 3-D image can be further processed to perform various measurements including volume estimation, and can be examined for abnormalities by the physician. Patient information, notes, and images may be stored for future retrieval.

Locations for biopsies may be selected by the physician, displayed on the 3-D image and 3-D rendered surface model, and stored. Previously stored 3-D models may be recalled and a stored 3-D model may be aligned or registered to the current 3-D model of the prostate.

Finally, the physician may attach a commercially available biopsy needle guide to the TRUS probe and use the probe and biopsy needle to perform tissue biopsy. Whenever the ultrasound machine is turned on by the physician, the live 2-D ultrasound image is displayed on the screen of 3-D Imaging Workstation during the biopsy. As the TRUS probe with attached needle guide is maneuvered by the physician, the position and orientation of the probe is tracked. The 3-D Imaging Workstation is able to add, display and edit plans for biopsy sites as well as an estimate of the probe position and needle trajectory relative to the 3-D image and 3-D rendered surface model of the prostate.

The 3-D Imaging Workstation offers the physician additional 3-D information for assessing prostate abnormalities, planning and implementing biopsy procedures. The additional image processing features are generated with minimal changes to previous TRUS probe based procedures, and the physician always has access to the live 2-D ultrasound image during prostate assessment or biopsy procedure.

Substantial Equivalence

The product's technical features are substantially equivalent to the 3-Dnet Suite (K063107) and the XELERIS 2 Processing and Review Workstation (K051673). The 3-D Imaging Workstation is primarily a software product that runs on a PC-based workstation. Image data is input to the devices and used to generate 3-D views and perform image processing. Like the two predicate devices, the software has image measurement, multi-planar reformatting, segmentation and image registration abilities, image storage and retrieval, as well as patient information management functions.

The 3-D Net Suite and XELERIS 2 are software products that accept multiple image data types including magnetic resonance, computed tomography and ultrasound. The 3-D Imaging Workstation has been designed for ultrasound imaging, using standard analog NTSC video input from commercially available transrectal ultrasound systems. The 3-D Imaging Workstation incorporates a mechanical device to track the position of an end fire ultrasound probe. Ultrasound system operation and transrectal probe movement all remain under manual control of the physician.

Testing and Performance Data

All product and engineering specifications were verified and validated. Test phantoms incorporating simulated prostates were developed and used to verify system performance through verification, validation (**Appendix D**) and benchmarking (**Appendix F**).

Conclusion

The results of comparing the intended use, function, technological characteristics, mode of operation and specifications of the 3-D Imaging Workstation with those of the two predicate devices demonstrate that the 3-D Imaging Workstation is substantially equivalent to existing products in the market today.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Eigen LLC
% Mr. Mark Job
Responsible Third Party Official
Regulatory Technology Services LLC
1394 25th Street NW
BUFFALO MN 55313

MAY - 1 2008

Re: K081093
Trade/Device Name: 3-D Imaging Workstation
Regulation Number: 21 CFR 892.1550
Regulation Name: Ultrasonic pulsed doppler imaging system
Regulatory Class: II
Product Code: LLZ
Dated: April 16, 2008
Received: April 17, 2008

Dear Mr. Job:

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

4 Indications for Use

Indications for Use

510(k) Number (if known): pending

Device Name: 3-D Imaging Workstation

Indications for Use:

The 3-D Imaging Workstation is intended to be used by physicians in the clinic or hospital for 2-D and 3-D visualization of ultrasound images of the prostate gland. Additional software features include patient data management, multi-planar reconstruction, segmentation, image measurement and 3-D image registration.

(Division Sign-Off)
Division of Reproductive, Abdominal and Radiological Devices
510(k) Number K081093

Prescription Use __X__ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

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