eigen K063846

Special 510(k) Summary

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JAN 26 2007

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Date Prepared: December 21, 2006

DEVICE INFORMATION

Trade/Proprietary Name:
Eigen Digital Subtraction Angiography (DSA) 2000, also referred to as the Eigen DSA 2000

Common/Classification Name: Image Processing System
21 CFR 892.2050
Class II
Device Product Code: LLZ

Predicate Device:
The Eigen DSA 2000 is substantially equivalent to another Eigen Imaging Device: the Digital 8. The DSA 2000 is a modification of Eigen's Digital 8, which was cleared under 510(k) K901956. The modifications made to the DSA 2000 do not alter the intended use or the fundamental scientific technology of the device.

Both the Eigen DSA 2000 and its predicate, the Digital 8, enhance images by performing the following functions:

- Noise Reduction
- Window/Level Feature
- Edge Enhancement
- Image Subtraction
- Still Image Display
- X-ray Lab Command Interface
- X-ray Lab Video Interface
- Data Archiving
- Data and Space Management
- Study Information (e.g., patient, site, and date)
- Configuration Menu
- Still Image Acquisition and Display
- Sequence Image Acquisition and Display, and
- Automated Contrast

The DSA 2000 device also offers the following additional features: Landscaping, Pixel Shifting, and Modality Work-List Support which are not in the predicate device. The DSA 2000 device does not offer the following functions which were in the original device: Magnification, Panning, Mix, Quantification and test patterns because it has been determined that there is not a customer demand for these features.

Product Description:
The Eigen Digital Subtraction Angiography® (DSA) is a real-time video acquisition device that can be added to an existing standard line-rate X-ray system and provides creation of photos and real-time digital subtraction taken from a mask image. The DSA acquires and transmits data to a DICOM workstation or PAC system. The data will then be available for display. The DSA output conforms to the DICOM 3.0XA Standard for lossless images.

The Eigen DSA is assembled on a Hewlett Packard (HP)/Intel platform and uses the Microsoft Windows XP® operating system.

Intended Use:
The Eigen DSA 2000 product is used in vascular imaging applications. During X-ray exposures, the DSA 2000 is used to acquire video images from the video display chain provided by the X-ray manufacturer's system. The images are stored in the DSA 2000 solid state memory, and written to the hard disk medium. Images are processed in real-time to provide increased image usability. The processing is primarily subtraction, but also includes window and level adjustments, as well as optional noise reduction, landscaping, and pixel Shifting. The Eigen DSA 2000 device is used in X-ray cardiology and radiology labs to enhance diagnostic capabilities of radiologists and cardiologists, with minimal intervention required by users to perform basic capture, playback, and archiving functions.

Test Discussion

Testing was performed at the module and system level according to written test protocols established before the testing was conducted. Test results were reviewed by designated technical professionals before release of the software.

Conclusion:

The test results support the conclusion that the DSA 2000 is substantially equivalent to its predicate device, D8. Actual device performance as tested internally conforms to the system requirements.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
9200 Corporate Blvd.
Rockville MD 20850

Eiden, LLC
% Ms. Natalie J. Kennel
Principal
NJK & Associates, Inc.
13721 Via Tres Vista
SAN DIEGO CA 92129

JAN 26 2007

Re: K063846
Trade/Device Name: Eigen Digital Subtraction Angiography (DSA) 2000
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulation Number: 21 CFR 892.1600
Regulation Name: Angiographic x-ray system
Regulatory Class: II
Product Code: LLZ and IZI
Dated: December 21, 2006
Received: December 27, 2006

Dear Ms. Kennel:

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.xxx	(Gastroenterology/Renal/Urology	240-276-0115
21 CFR 884.xxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 894.xxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 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 (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 Statement

510(k) Number: K013846

Device Name: Eigen Digital Subtraction Angiography (DSA) 2000

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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 Use** _____

(per 21 CFR 801.109)

David G. Lyman

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K063846