MAY 21 2003

K030544

510(K) Summary of Safety and Effectiveness

Date Prepared: February 12, 2003
Name of Contact Person: Omid Kia
Address: Sigma Vision Inc.
6001 Montrose Rd.
Suite 606
Rockville, Md. 20852
Phone: 301.770.0052
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Device trade name: RFX Fluoroscopic Digital Imaging System
Common name: Digital Radiography System
Classification Name: Image intensified fluoroscopic X-ray system

Device Description:

The RFX fluoroscopic digital imaging system allows the use of digital imaging to be applied to conventional X-ray system used in general fluoroscopy, interventional fluoroscopy, angiography and cardiac imaging areas. The system works by installing a CCD camera on the output port of the imaging intensifier and digitizing the video output of the image intensifier. The digital image can be displayed on the monitor; it can be stored to the hard drive, or sent to an external device such as a laser imager or Dicom Network Service Provider. The image can also be processed, including brightness and contrast, edge enhancement, zoom, and subtraction.

Intended Use:

The RFX fluoroscopic digital imaging system is a high resolution, digital imaging system designed for digital videography. It is intended to replace conventional film techniques in multipurpose or dedicated applications where general fluoroscopy, interventional fluoroscopy or angiography or cardiac imaging procedures are performed.

The RFX system allows the operator to view and enhance 1000 line fluoroscopy. High resolution digital spot images (1000 x 1000) may be acquired at single or rapid acquisition rates. Images may be viewed and enhanced enabling the operator to bring out diagnostic details difficult or impossible to see using conventional imaging techniques.

The RFX system enables the operator to print hardcopy images with laser printers, or send images over a network. The major system components are: fluoroscopic CCD camera, monitors, and image processor.

Conclusion drawn from comparison:

The RFX fluoroscopy digital imaging system can be considered to be substantially equivalent to:
INFIMED Inc. GOLDONE Fluoroscopic System (510K) – K963037
CMT Medical Technologies. SPOT / RAD System (510K), K991578 and K003434
and, virtually all of the features offered by the predicate devices are offered by the RFX product.

510(k) Number:

Unknown at this time

Device Name:

RFX Fluoroscopic Digital Imaging System.

Indications for Use:

The RFX Fluoroscopic digital imaging system is a high resolution, digital imaging system designed for digital videography. It is intended to replace conventional film techniques in multipurpose or dedicated applications where general fluoroscopy, interventional fluoroscopy or angiography or cardiac imaging procedures are performed.

The RFX system allows the operator to view and enhance 1000 line fluoroscopy. High resolution digital spot images (1000 x 1000) may be acquired at single or rapid acquisition rates. Images may be viewed and enhanced enabling the operator to bring out diagnostic details that might be difficult or impossible to see using conventional imaging techniques. Images can be stored locally for medium term storage.

The RFX system enables the operator to print hardcopy images with a laser printer or send images over a network for longer term storage. The major system components include: a fluoroscopic CCD Camera, monitors, and an image processor

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

Omid Kia, Ph.D.
Manager, Medical Imaging Products
Sigma Vision, Inc.
6001 Montrose Rd., Suite 606
ROCKVILLE MD 20852

MAY - 7 2012

Re: K030544
Trade/Device Name: RFX Fluoroscopic Digital Imaging System
Regulation Number: 21 CFR 892.1650
Regulation Name: Image-intensified fluoroscopic x-ray system
Regulatory Class: II
Product Code: OWB and JAA
Dated: February 12, 2003
Received: February 20, 2003

Dear Dr. Kia:

This letter corrects our substantially equivalent letter of May 21, 2003.

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 class II (Special Controls), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. 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 Parts 801 and 809); medical device reporting (reporting of

medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). 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 Parts 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely Yours,

Janine M. Morris
Acting Director
Division of Radiological Devices
Office of In Vitro Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

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510(k) Number (if known): K030544

Device Name: RFX Fluoroscopic Digital Imaging System

Indications For Use:

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Nancy C. Brogdon

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K030544

Prescription Use ✓ OR Over-The-Counter Use _____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)