FEB 1 2 2002

510(k) Summary of Safety and Effectiveness

K012490

Date Prepared: June 30, 2001
Name of Contact Person: Ralph J. Flatau
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Device trade name: Orion Fluoroscopic Imaging System
Common name: Digital Radiography System
Classification Name: Image intensified fluoroscopic X-ray system

Device Description:

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

Intended Use:

The InfiMed Orion Fluoroscopic 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 Orion system allows the operator to view and enhance 1000 line fluoroscopy. High resolution digital spot images (1024x1024)) 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 Orion system enables the operator to hardcopy image with a laser printer or send images over a network. The major system components include: a fluoroscopic TV camera, monitors, and an image processor.

Conclusions drawn from comparison:

The Orion fluoroscopic imaging system can be considered to be substantially equivalent to the InfiMed GoldOne Fluoroscopic System (510(k)-K963037) and the InfiMed FC2000 Fluoroscopic System (510(k) - K911454A). Virtually all of the features offered by either of the predicate devices are offered by the Orion product. There are a number of additional features that the Orion product offers, most of which are possible because of the increased power of the system. Some of these features require additional interfaces to acquire the data. In addition, to facilitate patient safety, some key interfaces have been changed from wires to fiber optics.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Mr. Brian N. Killoran
Quality Assurance Manager
InfiMed, Inc.
121 Metropolitan Drive
LIVERPOOL NY 13088

MAY - 7 2012

Re: K012490
Trade/Device Name: Orion Digital Imaging System
Regulation Number: 21 CFR 892.1650
Regulation Name: Image-intensified fluoroscopic x-ray system
Regulatory Class: Class II
Product Code: OWB and JAA
Dated: December 12, 2001
Received: December 21, 2001

Dear Mr. Killoran:

This letter corrects our substantially equivalent letter of February 12, 2002.

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 (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 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 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

Indications for Use Statement

510(k) Number K012490

Unknown at this time.

Device Name

Orion Fluoroscopic Imaging System.

Indications for Use

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The Orion system allows the operator to view and enhance 1000 line fluoroscopy. High resolution digital spot images (1024x1024) 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. Images can be stored locally for medium term storage.

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

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

Concurrence of CDRH, Office of Device Evaluation (DOE)

Prescription Use / Or Over the counter Use _____

Per 21 CFR 801.109 (Optional format 1-2-96)

Nancy C. Brogdon

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K012490