NOV - 9 1999

K992794

510(k) Summary of Safety and Effectiveness

Date Prepared: August 16, 1999
Name of Contact Person: Ralph J. Flatau
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121 Metropolitan Drive
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Device trade name: Stingray DR
Common name: Digital Radiography System
Classification Name: Solid State X-ray Imager (SSXI)

Device Description:

The Stingray DR system uses a flat panel x-ray detector that contains a CsI Scintillator and a Amorphous Si TFT array for conversion of X-rays into an electronic digital image. This system is to be used as a replacement for Screen film x-ray devices for X-ray images. The Stingray DR system has a Personal computer that is used for image storage and retrieval and image processing. The system allows for post processing of images. This allows for the potential to use images that might have been useless if taken on film due to, for example, incorrect technique since the Stingray DR system can post process the images, modify the output look up table and possibly bring out data that could not be seen under normal circumstances.

Intended Use:

The Stingray DR Solid State X-ray Imaging Device is intended for use in general radiographic examinations and applications wherever conventional screen-film systems may be used (excluding fluoroscopy, angiography, and mammography).

Conclusions drawn from comparison:

The Stingray DR system performs the same functions in the same environment as the other 510(k) approved devices. The Stingray DR system uses the same sensor as the Philips Digital Diagnost and the Siemens THORAX FD and MULTIX FD, the Trixell Pixium 4600 Digital Detector for Radiography. And as shown in the performance data section the InfiMed Stingray DR system has demonstrated the same resolution, up to 3.5 lp/mm as that claimed by the Philips and Siemens systems and better spatial resolution than the Canon system. This would imply that the only part of the Stingray DR system that would be different from the Philips system and the Siemens system, the defect compensation and image correction algorithms, results in the same image resolutions as the predicate devices.

Substantially equivalent devices and comparison:

Table of Comparison To 510(k) Approved SSXID

Feature/Item	InfiMed Stingray DR	Phillips Digital Diagnost	Siemens: THORAX FD and MULTIX FD	Canon Digital Radiography System	GE Revolution XQ/i
510(k) number	N/A	K982795	K983732	K981556	K982196
Flat Panel Producer	Trixell	Trixell	Trixell	Canon	GE
Detector Material	a-Si sensor array with CsI scintillator	a-Si sensor array with CsI scintillator	a-Si sensor array with CsI scintillator	Scintillator over a a-Si with a thin-film-transistor array	a-Si sensor array with CsI scintillator
Detector Dimensions	17" x 17"	17" x 17"	17" x 17"	17" x 17"	Not Available
Pixel Size	143 x 143 microns	143 x 143 microns	143 x 143 microns	160 x 160 microns	Not Available
Detector Element Matrix	2981 x 3021	2981 x 3021	2981 x 3021	2688 X 2688	Not Available
Dynamic Range	14 bits	14 bits	14 bits	14 bits	Not Available
Spatial Resolution	3.5 lp/mm	Up to 3.5 lp/mm	3.5 lp/mm	3.1 lp/mm	Not Available
External Connectivity	DICOM 3.0 compatible	DICOM 3.0 compatible	DICOM 3.0 compatible	DICOM 3.0 compatible	Not Available
Operator Console	Graphical User Interface based	Graphical User Interface based	Graphical User Interface based	Graphical User Interface based	Graphical User Interface based
Image Processor	Pentium based PC	Sun Ultra SPARC	Pentium based PC	Pentium based PC	Not Available
Image Storage	Hard Drive	Hard Drive	Hard Drive	Hard Drive	Not Available
Operating System	Windows NT	UNIX	Windows NT	Windows NT	Not Available
Total Image Processing time	30 seconds per image	Not Available	Not available	30 seconds per image	Not Available
ROI view	Yes	Unknown	Unknown	Yes	Unknown
Power Requirements	110/120V, 230/240V 50/60Hz	230V 50/60Hz	Not Available	110/120V, 230/240V 50/60Hz	Not Available

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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Ralph J. Flatau
Quality Assurance Manager
InfiMed., Inc.
121 Metropolitan Drive
Liverpool, NY 13088

Re: K992794
Stingray DR, Model 1 (SSXI System)
Dated: August 19, 1999
Received: August 19, 1999
Regulatory class: II
21 CFR 892.1650/Procode: 90 MQB

Dear Mr. Flatau:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we 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). 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 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 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 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4613. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification"(21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597, or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

CAPT Daniel G. Schultz, M.D.
Acting Director, Division of Reproductive,
Abdominal, Ear, Nose and Throat,
and Radiological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number K992794

~~Unknown at this time.~~

Device Name

Stingray DR Solid State X-ray Imaging Device.

Indications for Use

The Stingray Solid State X-ray Imaging Device is intended for use in general radiographic examinations and applications wherever conventional screen-film systems may be used (excluding fluoroscopy, angiography, and mammography).

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

Concurrence of CDRH, Office of Device Evaluation (DOE)

Prescription Use X Or Over the counter Use _____

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

David A. Legerron

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K992794