FEB 1 2 2003

510(k) Summary

K024147

The following information is provided following the format of 21 CFR 807.92 for the PaxScan 4030 Medical Digital Imaging System.

1. Submitter:

Varian Medical Systems
3100 Hansen Way M/S H055
Palo Alto, CA 94304-1129
Contact Name: Linda S. Nash
Corporate Director, Regulatory Affairs and
Quality Assurance
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Date: November 21, 2002

2. Device Name:

Classification Name:	Solid State X-ray Imaging Device
Common/Usual Name:	Flat Panel Digital Imager
Proprietary Name:	PaxScan 4030 Medical Digital Imaging System

3. Equivalent Devices:

Proprietary Names:	**Philips Bucky Vision**	**Canon X-Ray Digital Camera**	**Fugi CR System**	**Infimed Stringray DR**
510(K) Numbers:	**K982795**	**K981556**	**K993861**	**K992794**
Common Name:	Solid State X-Ray Imager			
Regulatory Class:	Class II, 21 CFR 892.~~6150~~ 1630			
Panel:	Radiology			
Product Code:	90MQB			

4. Device Description:

The PaxScan 4030 Medical Digital Imaging System is composed of an amorphous silicon flat planel imager, Pentium based computer, road runner card, trigger board, imaging software and a power supply. The digital imager uses a large-area amorphous silicon sensor array with a gadolinium oxysulfide scintillator. The 40 x 30 cm panel will display high quality images in approximately five seconds over a wide range of dose settings.

5. Statement of Intended Use:

The PaxScan 4030 Medical Digital Imaging System is intended for use in generating radiographic images of human anatomy. It is intended to replace film/screen or computed radiography in extremity and general-purpose procedures appropriate to the input field of view.

6. Comparison to substantially equivalent devices:
The PaxScan 4030 is substantially equivalent to:

Philips Bucky Vision	510(k) No. K982795
Canon X-Ray Digital Camera	510(k) No. K981556
Fuji CR System	510(k) No. K993861
Infimed Stingray DR	510(k) No. K992794

The following comparison chart depicts the comparison characteristics.

	Varian 4030R Flat Panel Imager	**Philips Bucky Vision**	**Canon X-Ray Digital Camera**	**Fuji CR System**	**InfiMed Stingray DR**
510(k) Number	N/A	K982795	K981556	K993861	K992794
Flat Panel Producer	Varian Medical Systems	Trixell	Canon	Fuji	Trixell
Detector Material	Amorphous Silicon Sensor Array with Gadolinium Oxysulfide Scintillator	Amorphous Silicon Sensor Array with Gadolinium Oxysulfide Scintillator	Scintillator over Amorphous Silicon Sensor with thin film Transistor Array	Photostimulable phosphor imaging plate europium activated barium flurohalide compounds in crystal form	Amorphous Silicon Sensor Array with Gadolinium Oxysulfide Scintillator
Dimensions	16" x 11.5"	17" x 17 "	17" x 17 "	17" x 17'	17" x 17"
Pixel Size	127 x 127 microns	143 x 143 microns	160 x 160 microns	Standard mode 200 microns ; high density mode 100 microns	143 x143 microns
Detector Element Matrix	2232 x 3200	2981 x3021	2688 x 2688	2140 x 2140	2981 x 3021
Dynamic Range	12 bits	14 bits	14 bits	10 bits	14 bits
Spatial Resolution	3.94 lp/mm	3.5 lp/mm	3.1 lp/mm	4.0+ lp/mm	3.5 lp/mm
External Connectivity	DICOM 3.0 Compatible	DICOM 3.0 Compatible	DICOM 3.0 Compatible	DICOM 3.0 Compatible	DICOM 3.0 Compatible
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 PC	Sun Ultra SPARC	Pentium PC	Pentium PC	Pentium PC
Image Storage	Hard Drive	Hard Drive	Hard Drive	Hard Drive	Hard Drive
Operating System	Windows NT, 2000	UNIX	Windows NT	Windows 98, NT	Windows NT
Image Processing Time	5 Seconds per Image	8 Seconds per Image	30 Seconds per Image	3-5 Minutes per Image	8 Seconds per Image
Power Requirements	100-240 VAC 50/60 Hz	230 V 50/60 Hz	110/120 V & 230/240 V 50/60 Hz	200-240 V 50/60 Hz 100-120 V 50/60 Hz	110/120 V & 230/240 V 50/60 Hz

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 1 2 2003

Ms. Linda S. Nash
Corporate Director, Regulatory Affairs
and Quality Assurance
Varian Medical Systems, Inc.
3100 Hansen Way
PALO ALTO CA 94304-1038

Re: K024147
Trade/Device Name: PaxScan 4030 Medical Digital Imaging System
Regulation Number: 21 CFR 892.1630
Regulation Name: Electrostatic x-ray imaging system
Regulatory Class: II
Product Code: 90 MQB
Dated: November 20, 2002
Received: December 16, 2002

Dear Ms. Nash:

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 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 the letter:

8xx.1xxx	(301) 594-4591
876.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4616
884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx	(301) 594-4616
892.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4654
Other	(301) 594-4692

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" (21CFR Part 807.97) you may obtain. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer 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,

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

Statement of Indications for Use

510(k) Number (if known): K024147

Device Name: PaxScan 4030 Medical Digital Imaging System

Indications For Use: The PaxScan 4030 Medical Digital Imaging System is intended for use in generating radiographic images of human anatomy. It is intended to replace film/screen or computed radiography in extremity and general-purpose procedures appropriate to the input field of view.

This device is intended for use by qualified medical personnel trained in radiology

Contraindications for Use: The use of the PaxScan 4030 Medical Digital Imaging System are contraindicated when, in the judgment of the physician, procedures would be contrary to the best interests of the patient.

(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) (Optional Format 1-2-96)

Nancy C Brogdon

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K024147