VARIAN | A partner for life
medical systems

APR 2 2 2013

Section 3: 510(k) Summary

Date Prepared:	02/07/2013
Contact Person:	Catherine Mulcahy Regulatory Affairs Manager
Telephone: **Fax:**	315-453-4545 x288 315-453-4550
Submitter Name:	Varian Medical Systems, X-Ray Products - InfiMed 121 Metropolitan Drive Liverpool, NY 13088
Device Trade Name:	Nexus DRF Digital X-ray Imaging System (with PaxScan 4343CB)
Common Name:	Digital X-ray Imaging System

Classification Name(s):	**Product Codes:**
Nexus DRF Digital X-ray Imaging System (with PaxScan 4343CB)	JAA, MQB

Predicate Device:	**510(k) Number:**	**Product Codes:**
Nexus DRF Digital X-ray Imaging System	K103416	JAA, MQB

Device Description:

The InfiMed i^{5}™ Digital X-ray Imaging System is a high resolution digital imaging system designed for digital X-ray imaging through the use of an X-ray detector. The InfiMed i^{5}™ Digital X-ray Imaging System is designed to support general radiography (excluding mammography), fluoroscopy, interventional fluoroscopy or angiography imaging procedures through a single common imaging platform.

The modified InfiMed i^{5}™ Digital X-ray Imaging System consists of an X-ray imaging receptor (any of the following: CCD Camera, Trixell Pixium 3543, Trixell Pixium 4600, Varian PaxScan 4336R, Varian PaxScan 4343R, Carestream Health Detector, Samsung LTX240AA01-A, Toshiba FDX 4343R, Trixell Pixium RF4343, Varian PaxScan 4343CB), computer, monitor, and the digital imaging system.

Intended Use:

The i^{5}™ Digital X-ray Imaging System is a high resolution digital imaging system intended to replace conventional film techniques, or existing digital systems, in multipurpose or dedicated applications specified below. The i^{5}™ Digital X-ray Imaging System enables an operator to acquire, display, process, export images to portable media, send images over a network for long term storage and distribute hardcopy images with a laser printer. Image processing algorithms enable the operator to bring out diagnostic

VARIAN medical systems | A partner for life

details difficult to see using conventional imaging techniques. Images can be stored locally for temporary storage. The i5™ Digital X-ray Imaging System has the ability to interface with a variety of image receptors from CCD cameras to commercially available flat panel detectors. The major system components include an image receptor, computer, monitor and imaging software.

For the DR application, the InfiMed i5™ Digital X-ray Imaging System is intended for use in general radiographic examinations and applications (excluding fluoroscopy, angiography, and mammography).

For the RF/DSA application, the InfiMed i5™ Digital X-ray Imaging System is intended for use where general fluoroscopy, interventional fluoroscopy or angiography imaging procedures are performed.

Technological Characteristics Comparison:

The modified device supports the same modalities as the predicate device with the same components or imaging concepts, and delivers equivalent or better image quality as the predicate device. The comparison chart reveals that functions performed by the predicate device are performed by the modified i5™ Digital X-ray Imaging System. The modified device, Nexus DRF Digital X-ray Imaging System (with PaxScan 4343CB), has the ability to interface with an additional image receptor, Varian PaxScan 4343CB. Therefore, the modified device is substantially equivalent to the predicate device.

Non-clinical Tests Discussion:

Validation was completed in accordance with the Validation Protocols included with this submission. Protocols were designed, executed and documented according to the Design Validation process with predetermined test methods and corresponding acceptance criteria. In conclusion, all release criteria have been met and the modified i5™ Digital X-ray Imaging System is as safe and effective as the predicate device and does not raise different questions of safety and effectiveness.

Clinical Tests Discussion:

Clinical Data submitted is consistent with FDA guidance document "Guidance for Industry and/or for FDA Reviewers/Staff and/or Compliance: Guidance for the Submission of 510(k)'s for Solid State X-ray Imaging Devices" available at the website http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm073781.pdf.

Conclusion:

Based upon the results of Verification and Validation testing, the Nexus DRF Digital X-ray Imaging System (with PaxScan 4343CB) has no new indications for use, has no significant technological differences, and is as safe and effective as, does not raise different questions of safety and effectiveness and is therefore substantially equivalent to the above listed current legally marketed predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

April 22, 2013

Varian Medical Systems, X-Ray Products - InfiMed
% Ms. Catherine Mulcahy
Regulatory Affairs Manager
121 Metropolitan Drive
LIVERPOOL NY 13088

Re: K130318
Trade/Device Name: Nexus DRF Digital X-ray Imaging System
Regulation Number: 21 CFR 892.1650
Regulation Name: Image-intensified fluoroscopic x-ray system
Regulatory Class: II
Product Code: JAA, MQB
Dated: February 28, 2013
Received: March 7, 2013

Dear Ms. Mulcahy:

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

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); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 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/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Janine M. Morris
Director, Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K130318

Device Name: Nexus DRF Digital X-ray Imaging System (with PaxScan 4343CB)

Indications for Use:

The InfiMed i^{5}™ Digital X-ray Imaging System is a high resolution digital imaging system intended to replace conventional film techniques, or existing digital systems, in multipurpose or dedicated applications specified below. The i^{5}™ Digital X-ray Imaging System enables an operator to acquire, display, process, export images to portable media, send images over a network for long term storage and distribute hardcopy images with a laser printer. Image processing algorithms enable the operator to bring out diagnostic details difficult to see using conventional imaging techniques. Images can be stored locally for temporary storage. The i^{5}™ Digital X-ray Imaging System has the ability to interface with a variety of image receptors from CCD cameras to commercially available flat panel detectors. The major system components include an image receptor, computer, monitor and imaging software.

For the DR application, the InfiMed i^{5}™ Digital X-ray Imaging System is intended for use in general radiographic examinations and applications (excluding fluoroscopy, angiography, and mammography).

For the RF/DSA application, the InfiMed i^{5}™ Digital X-ray Imaging System is intended for use where general fluoroscopy, interventional fluoroscopy or angiography imaging procedures are performed.

Prescription Use ✓ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of In Vitro Diagnostics and Radiological Health (OIR)

(Division Sign Off)
Division of Radiological Health
Office of In Vitro Diagnostics and Radiological Health

510(k) K130318