DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Varian Medical Systems, X-ray Products – InfiMed
% Ms. Catherine Mulcahy
Regulatory Affairs Manager
121 Metropolitan Drive
LIVERPOOL NY 13088

September 6, 2016

Re: K161459
Trade/Device Name: Nexus DR™ Digital X-ray Imaging System (with PaxScan 4336Wv4)
Regulation Number: 21 CFR 892.1680
Regulation Name: Stationary x-ray system
Regulatory Class: II
Product Code: MQB
Dated: August 5, 2016
Received: August 8, 2016

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 contact the Division of Industry and Consumer Education 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. 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 Industry and Consumer Education 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,

Robert Ochs, Ph.D.
Director
Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K161459

Device Name
Nexus DR™ Digital X-ray Imaging System (with PaxScan 4336Wv4)

Indications for Use *(Describe)*
The Varian Nexus DR™ 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 Nexus DR™ 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 major system components include an image receptor, computer, monitor and imaging software.

The Varian Nexus DR™ Digital X-ray Imaging System is intended for use in general radiographic examinations and applications (excluding fluoroscopy, angiography, and mammography).

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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Section 3: 510(k) Summary

Date Prepared: 5/25/2016

Contact Person: Catherine Mulcahy
Regulatory Affairs Manager

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Submitter Name: Varian Medical Systems, X-Ray Products - InfiMed
121 Metropolitan Drive
Liverpool, NY 13088

Device Trade Name: Nexus DR™ Digital X-ray Imaging System
(with PaxScan 4336Wv4)

Common Name: Digital Radiographic System
Regulation: 21 CFR 892.1680

Classification Name: Stationary X-ray System
Primary Product Code: MQB

Primary Predicate Device:	510(k) Number:	Product Code:
Stingray DR Digital Radiographic System	K992794	MQB

Reference Predicate Device:	510(k) Number:	Product Code:
Nexus DRF™ Digital X-ray Imaging System	K130318	JAA, MQB

Device Description:

The Varian Nexus DR™ 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 Varian Nexus DR™ Digital X-ray Imaging System is designed to support general radiographic (excluding fluoroscopy, angiography, and mammography) procedures through a single common imaging platform.

The modified device consists of an X-ray imaging receptor, Varian PaxScan 4336Wv4, computer, monitor, and the digital imaging software.

Intended Use:

The Varian Nexus DR™ 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 Nexus DR™ 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 major system components include an image receptor, computer, monitor and imaging software.

The Varian Nexus DR™ Digital X-ray Imaging System is intended for use in general radiographic examinations and applications (excluding fluoroscopy, angiography, and mammography).

Technological Characteristics Comparison:

The Nexus DR™ Digital X-ray Imaging System (with PaxScan 4336Wv4) supports the same modality as the predicate devices with similar components or imaging concepts, and delivers equivalent or better image quality as the predicate devices. The comparison chart below reveals that functions performed by the predicate devices are performed by the modified device for the DR application. Therefore, the modified device is substantially equivalent to the predicate devices.

However, the modified device, Nexus DR™ Digital X-ray Imaging System (with PaxScan 4336Wv4), has the ability to interface with the Varian PaxScan 4336Wv4 wireless detector with vTrigger capability. The Nexus DR™ Digital X-ray Imaging System (with PaxScan 4336Wv4) is not integrated with the x-ray generator. With vTrigger, there is no intercepting of the Prep/Expose signals from the generator. The receptor is placed in a "ready" mode by the user and on the Nexus DR™ User Interface. The user operates the generator (technique and exposure switch) when the receptor indicates it is "ready." The receptor captures the exposure once it arrives and acquires the data.

Comparison Chart:

Feature/Item	**Nexus DRF™ Digital X-ray Imaging System**	**Stingray DR Digital Radiographic System**	**Nexus DR™ Digital X-ray Imaging System**
Device Type	**Reference Predicate**	**Primary Predicate**	**Subject Device**
510 (k) Number	**K130318**	**K992794**	**K161459**
Flat Panel Detector	Varian PaxScan 4343R	Trixell Pixium 4600	Varian PaxScan 4336Wv4
Detector Material	a-Si sensor array with CsI or Gd_2O_2S:TB scintillator	a-Si sensor array with CsI scintillator	a-Si sensor array with CsI or Gd_2O_2S:TB scintillator
Detector Dimensions	17" x 17"	17" x 17"	17" x 14"
Pixel Size	139 x 139 microns	143 x 143 microns	139 x 139 microns
Detector Element Matrix	3072 x 3072	2981 x 3021	3072 x 2560
Dynamic Range	14 bits	14 bits	16 bits

Uniform Density	1.63	N/A	1.52
Spatial Resolution	3.2 lp/mm	3.51 lp/mm	3.2 lp/mm
Sensitivity	128 @ 1.1uGy/frame 395 @ 3.9uGy/frame 1060 @ 10uGy/frame 3143 @ 30uGy/frame *(14-bit reference panel)*	N/A	540 @ 1.1uGy/frame 1206 @ 3.9uGy/frame 4290 @ 10uGy/frame 12804@ 30uGy/frame *(16-bit subject panel)*
Signal to Noise Ratio	67 @ 2.8uGy/frame 96 @ 7uGy/frame 147 @ 17uGy/frame 275 @ 50uGy/frame	N/A	73 @ 2.8uGy/frame 117 @ 7uGy/frame 174 @ 17uGy/frame 285 @ 50uGy/frame
Modulation Transfer Function	0.521 @ 1cycle/mm 0.206 @ 2cycles/mm 0.08 @ 3cycles/mm	N/A	0.551 @ 1cycle/mm 0.234 @ 2cycles/mm 0.099 @ 3cycles/mm
Detective Quantum Efficiency	0.242 @ 1cycle/mm 0.125 @ 2cycles/mm 0.04 @ 3cycles/mm	N/A	0.232 @ 1cycle/mm 0.15 @ 2cycles/mm 0.07 @ 3cycles/mm
External Connectivity	DICOM 3.0 Compatible	DICOM 3.0 Compatible	DICOM 3.0 Compatible
Operator Console	Graphical User Interface	Graphical User Interface	Graphical User Interface
Image Processor	Intel Based PC, nvidia GPU	Pentium Based PC	Intel CPU Based PC
Image Storage	Hard Drive	Hard Drive	Hard Drive
Operating System	Windows 7	Windows NT	Windows 10
Total Image Processing Time	10 seconds per image	30 seconds per image	10 seconds per image
Power Requirements	110/120V, 230/240V, 50/60 Hz	110/120V, 230/240V, 50/60 Hz	110/120V, 230/240V, 50/60 Hz

Non-clinical Tests Discussion:

Non-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.

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 Nexus DR™ Digital X-ray Imaging System (with PaxScan 4336Wv4) is as safe and effective as the predicate devices 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 DR™ Digital X-ray Imaging System (with PaxScan 4336Wv4) 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 devices.