DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

May 17, 2017

Varex Imaging Corporation
% Ms. Catherine Mulcahy
Regulatory Affairs Manager
121 Metropolitan Drive
LIVERPOOL NY 13088

Re: K171138
Trade/Device Name: Nexus DR™ Digital X-ray Imaging System (with Grid Suppression)
Regulation Number: 21 CFR 892.1680
Regulation Name: Stationary x-ray system
Regulatory Class: II
Product Code: MQB
Dated: April 17, 2017
Received: April 18, 2017

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,

For

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)*

K171138

Device Name
Nexus DR™ Digital X-ray Imaging System (with Grid Suppression)

Indications for Use *(Describe)*

The Varex 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 Varex 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: 5/5/17

Contact Person: Catherine Mulcahy
Regulatory Affairs Manager

Telephone: 315-234-6853
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Submitter Name: Varex Imaging Corporation
121 Metropolitan Drive
Liverpool, NY 13088

Subject Device
Trade Name: Nexus DR™ Digital X-ray Imaging System
(with Grid Suppression)
Common Name: Digital Radiographic System
Regulation: 21 CFR 892.1680
Classification Name: Stationary X-ray System
Class: II
Primary Product Code: MQB

Primary Predicate 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
Class: II
Primary Product Code: MQB
510(k) Number: K161459

Device Description:

The Varex 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 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.

The Varex Nexus DR™ Digital X-ray Imaging System is a configurable product platform designed to allow Varex to leverage the common components of digital X-ray imaging systems from which the following medical modalities can be served: General Radiography (excluding fluoroscopy, angiography, and mammography). The Nexus

DR™ Digital X-ray Imaging System is then configured to function on a computer with modality specific components, functionality and capabilities to complete the specific product package.

Like the predicate device, the modified Nexus DR™ Digital X-ray Imaging System is in a class of devices that all use similar technology to acquire digital radiographic images. These devices convert X-rays into visible light that shines onto a TFT array, which converts the visible light into a digital electronic signal. This process is ultimately used for the same purpose as Radiographic film, to create an X-ray image.

Identical to the predicate device, the modified device is capable of interfacing with the same wireless PaxScan 4336Wv4 flat panel detector in vTrigger Mode.

However, the modified device is also capable of operating in RAD Mode utilizing an external I/O box to interface with compatible X-ray generators, in non-integrated mode. Through the use of a digital flat panel detector, and a non-integrated generator, the Nexus DR™ Digital X-ray Imaging System (with Grid Suppression) is capable of acquiring digital radiographic images, processing and then displaying them in high quality for clinical diagnosis. The Nexus DR™ Digital X-ray Imaging System can then store the images on the local computer, archive them to CD/DVD media, transfer them to Hard Copy format via DICOM printers, or transfer them to PACS reviewing stations in DICOM format.

Anti-scatter grids play an important role for enhancing image quality in radiography by transmitting a majority of primary radiation and selectively rejecting scattered radiation. When anti-scatter grids are utilized by the end user, the modified device includes an additional feature that can detect and suppress the line artifacts caused by these grids.

Indications for Use:

The Varex 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 Varex 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 Grid Suppression) supports the same modality as the predicate device with similar components or imaging concepts, has the same Indications for Use as the predicate device, and delivers equivalent image quality as the predicate device. The comparison chart below reveals that functions performed by the predicate device are performed by the modified device for the DR application. Therefore, the modified device is substantially equivalent to the predicate device.

However, the modified device, Nexus DR™ Digital X-ray Imaging System (with Grid Suppression), has the additional ability to interface with the Varian PaxScan 4336Wv4 wireless detector in RAD Mode with a new additional grid suppression feature. Grid Suppression is not dependent on panel acquisition mode.

The Nexus DR™ Digital X-ray Imaging System (with Grid Suppression) operating in RAD Mode (Panel Acquisition Mode) is designed to communicate with X-ray generators that provide Select, Prep and Request signals. The Nexus DR™ Digital X-ray Imaging System (with Grid Suppression) utilizes an external I/O box to interface with compatible X-ray generators; not integrated. If an X-ray generator does not provide Select, Prep and Request signals, vTrigger Mode (AED) is used; thus no connection to the generator is required.

Anti-scatter grids are used in radiography to improve image quality by reducing the amount of scatter X-rays from reaching the imaging receptor which, in turn, increases image contrast. The Nexus DR™ Digital X-ray Imaging System (with Grid Suppression) uses an intuitive software algorithm to detect and suppress the line artifacts caused by anti-scatter grids. Only minor modifications were necessary to implement Grid Suppression software for this device. All other features and functions remain unchanged.

Comparison Chart:

Feature/Item	Nexus DR™ Digital X-ray Imaging System (PaxScan 4336Wv4)	Nexus DR™ Digital X-ray Imaging System (Grid Suppression)
Device Type	**Predicate Device**	**Subject Device**
510 (k) Number	**K161459**	**TBD**
Flat Panel Detector	Varian PaxScan 4336Wv4	Same
Detector Material	a-Si sensor array with CsI or Gd_2O_2S:TB scintillator	Same
Detector Dimensions	17” x 14”	Same
Pixel Size	139 x 139 microns	Same
Detector Element	3072 x 2560	Same

Matrix		
Dynamic Range	16 bits	Same
Uniform Density	1.52	Same
Spatial Resolution	3.2 lp/mm	Same
Sensitivity	540 @ 1.1uGy/frame 1206 @ 3.9uGy/frame 4290 @ 10uGy/frame 12804@ 30uGy/frame *(16-bit subject panel)*	Same
Signal to Noise Ratio	73 @ 2.8uGy/frame 117 @ 7uGy/frame 174 @ 17uGy/frame 285 @ 50uGy/frame	Same
Modulation Transfer Function	0.551 @ 1cycle/mm 0.234 @ 2cycles/mm 0.099 @ 3cycles/mm	Same
Detective Quantum Efficiency	0.232 @ 1cycle/mm 0.15 @ 2cycles/mm 0.07 @ 3cycles/mm	Same
External Connectivity	DICOM 3.0 Compatible	Same
Operator Console	Graphical User Interface	Same
Image Processor	Intel CPU Based PC	Same
Image Storage	Hard Drive	Same
Operating System	Windows 10	Same
Total Image Processing Time	10 seconds per image	Same
Power Requirements	110/120V, 230/240V, 50/60 Hz	Same
Grid Suppression	No	Yes
Panel Acquisition Mode	vTrigger	vTrigger or RAD Mode
Generator Interface	Not Applicable	Applicable*

* Generators meeting these requirements can be interfaced with the Nexus DR™ Digital X-ray Imaging System (with Grid Suppression) in RAD Mode.

- The Generator/Handswitch/Console shall (allow the user to) provide Select, Prep and Request radiographic exposure signals in the form of digital signals.
- The Generator shall be capable of accepting Expose signals available as relay outputs.

For example, the following generators are capable of interfacing with the Nexus DR™ Digital X-ray Imaging System (with Grid Suppression) in RAD Mode.

Manufacturer	Model
Bennett	HFQ-1250P
Bennett	HFQ-1000
CGR	Prestilix 1600
CPI	CMP200
CPI	Indico 100
CPI	IQ
CPI	Millennia
Continental	TM
DELL	ATC 525
DELL	MP-500
DELL	ATC 725
Electromed	All Series
EMD	Epsilon
Gendex	ATC 525
General Electric	MVP
General Electric	MPS
Holigic	TM
IMD	Atlas 100-30
Gendex	ATC 725
K&S Rontgenwerks	HFe
Philips	Optimus 80
Picker	Convix
Picker	MTS
Picker	Synergen
Quantum	Odyssey
Sedecal	HF
Sedecal	SHF
Shimadzu	UD150-10
Siemens	Polydoros 80
Siemens	Polydoros IT
Summit	Innovet
Spellman	HFE
Toshiba	KXO80
Trex	TM
Universal	MP-500

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 Grid Suppression) 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.

Clinical images were not necessary to establish substantial equivalence based on the modifications to the device (the PaxScan 4336Wv4 Flat Panel Detector uses identical technology as the predicate device image detector), and bench testing results provide enough evidence that the subject device works as intended.

Standards and Guidance Documents:

Electrical Safety and EMC Standards
The modified device conforms to these consensus standards and has passed all relevant required testing:

- AAMI ANSI ES60601-1:2005/(R)2012 and A1:2012, C1:2009/(R)2012 and A2:2010/(R)2012; Medical electrical equipment – Part 1: General requirements for basic safety and essential performance

- IEC 60601-1-2 Edition 3: 2007-03; Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests (2007)

Data Storage and Exchange Standards
The Nexus DR™ Digital X-ray Imaging System is designed to meet American College of Radiology / American College of Cardiology / National Electrical Manufacturers Association DICOM, Version 3.0, Parts 1 through 8, Part 10 (Media Storage and File Formats), Part 11 (Media Storage Applications Profiles) and Part 12 (CD-R Annex):

- NEMA PS 3.1 - 3.20; Digital Imaging and Communications in Medicine (DICOM) Set (2011)

Radiation Control

The Nexus DR™ Digital X-ray Imaging System meets the requirements of the Radiation Performance Standards of 21 CFR Subchapter J, applicable Sections 21 CFR 1020.30, 1020.31 and 1020.32.

Any video monitors chosen for this application meet the requirements of the Radiation Performance Standards of 21 CFR Subchapter J, applicable Section 21 CFR 1020.10.

Optical disk storage devices (reader and writer) comply with Radiation Performance Standards of 21 CFR Subchapter J, applicable Section 21 CFR 1040.10.

Guidance

The following guidance documents were considered and utilized in the development of the modified device. Applicable identified requirements derived from these guidance documents have been met.

- Guidance for the Submission of 510(k)'s for Solid State X-ray Imaging Devices
- How to Prepare a Special 510(k)
- Guidance for Content of Premarket Submissions for Software Contained in Medical Devices
- Deciding When to Submit a 510(k) for a Change to and Existing Device
- Pediatric Information for X-ray Imaging Device Premarket Notifications
- Applying Human Factors and Usability Engineering to Medical Devices
- Use of Symbols in Medical Device Labeling
- Content of Premarket Submissions for Management of Cybersecurity in Medical Devices
- Refuse to Accept Policy for 510(k)s
- eCopy Program for Medical Device Submissions
- Global Unique Device Identification Database (GUDID)

Conclusion:

Based upon the results of Verification and Validation testing, the Nexus DR™ Digital X-ray Imaging System (with Grid Suppression) 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.