Varex Imaging Corporation
% Mr. Michael G. Van Ryn
Regulatory Affairs Analyst
121 Metropolitan Drive
LIVERPOOL NY 13088

March 8, 2019

Re: K190146
Trade/Device Name: Nexus DR Digital X-ray Imaging System (with Integrated Generator)
Regulation Number: 21 CFR 892.1680
Regulation Name: Stationary x-ray system
Regulatory Class: Class II
Product Code: MQB, KPR
Dated: January 22, 2019
Received: January 29, 2019

Dear Mr. Van Ryn:

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see

https://www.fda.gov/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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 comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Michael D. O'Hara For

Thalia Mills, 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K190146

Device Name
Nexus DR with Integrated Generator

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 hard-copy 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 Revised: 03/06/2019

Contact Person: Michael Van Ryn
Regulatory Affairs Manager
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Submitter Name: Varex Imaging Corporation
121 Metropolitan Drive
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Subject Device

Trade Name: Nexus DR. Digital X-ray Imaging System (with Integrated Generator)
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 Stitching)
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: K183212

Reference Predicate Device:
Trade Name: CPI Rad Vision
Common Name: Digital Radiographic System
Regulation: 21 CFR 892.1680
Classification Name: Stationary X-ray System
Class: II
Primary Product Code: KPR
510(k) Number: K122726

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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, computer, monitor, and the digital imaging software and the optional Integrated Generator GUI 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 flat panel detectors in RAD Mode without utilizing an external I/O box to interface with the X-ray generator. The modified device also retains the ability to apply the grid suppression feature.

Similar to the already cleared Nexus DR™ Digital X-ray Imaging System with Stitching and CPI Rad Vision the modified device, Nexus DR™ Digital X-ray Imaging System (with Integrated Generator), has the same intended use for the DR application. The modified device, however, has the ability to allow the operator to control the CPI CMP200 X-ray generator through the Nexus DR™ Graphical User Interface (GUI). All control functions currently available to the operator on the CPI Membrane Rad Console will be available via the Nexus DR GUI. 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.

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).

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Technological Characteristics Comparison:

The Nexus DR. Digital X-ray Imaging System (with Integrated Generator) 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 Integrated Generator), has the ability to allow the operator to control the CPI CMP200 X-ray generator through the Nexus DR™ Graphical User Interface (GUI). All control functions currently available to the operator on the CPI Membrane Rad Console will be available via the Nexus DR GUI. All other features and functions remain unchanged.

Through the use of a digital flat panel detector, the Nexus DR™ Digital X-ray Imaging System (with Integrated Generator) 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.

Nexus DR™ Digital X-ray Imaging System (with Integrated Generator) is an additional feature to the stationary X-Ray system which allows the operator to control the CPI CMP200 X-ray generator through the Nexus DR™ Graphical User Interface (GUI). All control functions currently available to the operator on the CPI Membrane Rad Console will be available via the Nexus DR GUI. Acquired imaging can be stored on the local computer, archived to CD/DVD, transferred to Hard Copy format via DICOM printers, or transferred to a PACS reviewing station in DICOM format.

Comparison Chart:

Feature/Item	Nexus DR™ Digital X- ray Imaging System (with Stitching)	CPI Rad Vision	Nexus DR™ with Integrated Generator
Device Type	**Primary Predicate Device**	**Secondary Predicate Device**	**Subject Device**
510 (k) Number	**K183212**	**K122726**	**Pending**
Integrated CPI CMP200 Generator	No	Yes	Same as Secondary Predicate Device
Panel Acquisition Mode	Vtrigger or RAD mode	Generator synchronization	RAD mode only
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	Windows XP	Same as Primary Predicate Device
Digital Imaging Systems	Radiography modes (remote control) – using a large flat panel detector		Same
Digital Imaging	Radiography		Same
Supported Flat panels	Varian PaxScan 4343Rv3 Varian PaxScan 4336Wv4	Varian PaxScan 4343R(v1)* Varian PaxScan 4336R(v1)*	Same as K183212
Power Requirements	110/120V, 230/240V, 50/60 Hz		Same

*these panels are not supported by the Subject Device (Nexus DR v4.3.0)

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.

Both non-clinical Verification and Validation testing was completed. Verification confirmed the technical functionality of the Nexus DR Integrated Generator design requirements while, Validation confirmed the design requirements of the Nexus DR Integrated Generator feature from a clinical workflow perspective.

Non-clinical Verification testing of the Nexus DR Integrated Generator feature was completed using a simulated (bench test) clinical environment and confirmed all design requirement associated with the integrated generator feature. Verification included testing service settings for configuring the generator, configuration and modification of the acquisition profile generator settings, confirming image acquisition, as well as a full system regression.

Non-clinical Validation testing was performed using a standard clinical workflow in a simulated (bench test) clinical environment to test the Integrated Generator feature in combination with other Nexus DR functions such as, Worklist Patients with Multiple Studies, Auto Position Advance and Auto DICOM Send. The validation of the Integrated Generator feature included confirming the initial generator settings or exposure factors upon opening a new patient study, confirming the correct detector is selected based on the active generator workstation, and confirming display of the generator data in the image overlay after an image acquisition has completed. The generator settings include: Workstation, focal spot, exposure mode, and technique factors.

Non-clinical Verification and Validation testing was completed in accordance with the Verification and Validation Protocols included with this submission. Protocols were designed, executed and documented per the Design Control Process with predetermined test methods and corresponding acceptance criteria. All associated tests described above completed successfully without errors and the both devices preformed as intended. In conclusion, all release criteria have been met and the Nexus DR Digital X-ray Imaging System with Integrated Generator is as safe and effective as the predicate devices and does not raise different questions of safety and effectiveness.

The table below outlines where the submitted verification and validation documentation are located.

Verification Documents	VOL_010_Appendix J Verification Tests
Validation Documents	VOL_011_Appendix K Validation Tests

Clinical Tests Discussion:

No clinical testing was performed as a result of this modification. However, Usability Testing was performed and the results of the Usability Tests can be found in VOL_011_Appendix K Validation Tests.

Please refer to **Appendix O** for the completed form "FDA 3674 Certification of Compliance with Clinical Trials".

Standards and Guidance Documents:

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

- IEC 60601-1-2 Edition 4.0 2014-02, Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests.

- IEC 60601-2-54 CONSOLIDATED VERSION Edition 1.1 2015-04, Medical electrical equipment - Part 2-54: Particular requirements for the basic safety and essential performance of X-ray equipment for radiography and radioscopy [Including: Amendment 2 (2018)]
- 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 (2016)

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)

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Conclusion:

Based upon the results of Verification and Validation testing, the Nexus DR. Digital X-Ray Imaging System (with Integrated Generator) 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.