May 29, 2026

Varex Imaging Corporation
% Leah Van De Water
Regulatory Affairs Analyst
1678 S. Pioneer Rd.
SALT LAKE CITY, UT 84104

Re: K253103
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: Class II
Product Code: JAA, MQB
Dated: April 30, 2026
Received: April 30, 2026

Dear Leah Van De Water:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (Preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the Quality Management System Regulation (QMSR) (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). 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 (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-

assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

for 

Lu Jiang Ph.D.
Assistant Director
Diagnostic X-Ray Systems Team
DHT8B: Division of Radiological Imaging Devices and Electronic Products
OHT8: Office of Radiological Health
Office of Product Evaluation and Quality
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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K253103

Device Name
Nexus DRF Digital X-ray Imaging System

Indications for Use *(Describe)*
The Varex Nexus DRF Digital X-Ray Imaging System enables an operator to acquire, display, process, and export combined medical x-ray / fluoroscopy images for long-term storage. The Varex Nexus DRF Digital X-Ray Imaging System is intended for use in general radiographic examinations and applications (excluding 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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) #: K253103

510(k) Summary

Prepared on: 2026-04-30

Contact Details

21 CFR 807.92(a)(1)

Applicant Name	Varex Imaging Corporation
Applicant Address	1678 South Pioneer Road Salt Lake City UT 84104 United States
Applicant Contact Telephone	585-356-0366
Applicant Contact	Leah Van De Water
Applicant Contact Email	leah.vandewater@vareximaging.com

Device Name

21 CFR 807.92(a)(2)

Device Trade Name	Nexus DRF Digital X-ray Imaging System
Common Name	System, X-Ray, Fluoroscopic, Image-Intensified
Classification Name	Image-intensified fluoroscopic x-ray system
Regulation Number	892.1650
Product Code(s)	JAA, MQB

Legally Marketed Predicate Devices

21 CFR 807.92(a)(3)

Predicate #	Predicate Trade Name (Primary Predicate is listed first)	Product Code
K130318	Nexus DRF Digital X-ray Imaging System	JAA

Device Description Summary

21 CFR 807.92(a)(4)

The Nexus DRF Digital X-ray Imaging System (Nexus DRF) is a high resolution digital imaging system used in general radiographic and fluoroscopic applications. The major components include a detector, computer, and imaging software.

Nexus DRF uses a solid-state X-ray detector to capture digital images of anatomy penetrated by an incident X-ray beam. A host X-ray system generates the X-ray beam, which passes through a patient and strikes the detector. The detector converts the X-ray energy to digital image data that is then passed to the computer. The computer processes the image data, displays the image to the user, and provides temporary storage for image data and associated patient information, which can be imported from a work list or entered manually. When the user has finished applying processing, annotation, and measurement features of the imaging software, the images can be archived or printed to appropriate DICOM compliant devices.

The modification to the Nexus DRF includes changes to support the integration of a new detector and software feature improvements.

Intended Use/Indications for Use

21 CFR 807.92(a)(5)

The Varex Nexus DRF Digital X-Ray Imaging System enables an operator to acquire, display, process, and export combined medical x-ray / fluoroscopy images for long-term storage. The Varex Nexus DRF Digital X-Ray Imaging System is intended for use in general radiographic examinations and applications (excluding mammography).

Indications for Use Comparison

21 CFR 807.92(a)(5)

The indications for use of the modified device and predicate device are substantially equivalent. The change is limited to only the wording.

Technological Comparison

21 CFR 807.92(a)(6)

The technological characteristics of the modified device and predicate device are substantially equivalent. The modified device includes changes to support the integration of a new detector and software feature improvements. The design, principle of operation, and functionality is similar for the modified device when compared to the predicate device.

Non-Clinical and/or Clinical Tests Summary & Conclusions

21 CFR 807.92(b)

The modified Nexus DRF Digital X-ray Imaging System complies with relevant safety standards such as IEC 60601-1 and IEC 60601-1-2.

Non-clinical testing was performed according to according to Guidance for the Submission of 510(k)s for Solid State X-ray Imaging Devices - Guidance for Industry and Food and Drug Administration Staff. The modified device was determined to be substantially equivalent to the predicate device for the parameters measured.

Image quality testing was performed with anthropomorphic phantoms for the comparison with the predicate device. A US board certified Radiologist reviewed the image pairs for image quality and provided an overall assessment the image sets collectively are substantially equivalent to the predicate device.

Software and cybersecurity testing was performed according to Guidance for Content of Premarket Submissions for Device Software Functions - Guidance for Industry and Food and Drug Administration Staff and Guidance for Cybersecurity in Medical Devices: Quality System Considerations and Content of Premarket Submissions. All testing was performed according to the Verification & Validation Plans and the expected results were met in each case.

Clinical testing was not applicable.

The successful testing demonstrates the modified Nexus DRF Digital X-ray Imaging System is as safe and effective and performs substantially equivalent to the predicate device (K130318) when used in accordance with its labeling.