Radiology Information Systems, Inc.
% Daniel Kamm, P.E.
Principal Engineer
Kamm & Associates
8870 Ravello Ct.
NAPLES FL 34114

August 16, 2019

Re: K191504
Trade/Device Name: PowerDR™
Regulation Number: 21 CFR 892.1650
Regulation Name: Image-intensified fluoroscopic x-ray system
Regulatory Class: Class II
Product Code: JAA, MQB
Dated: June 3, 2019
Received: June 6, 2019

Dear Mr. Kamm:

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/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); 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 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

Thalia T. Mills, Ph.D.
Director
Division of Radiological Health
OHT7: Office of In Vitro Diagnostics
and 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K191504

Device Name
PowerDR™

Indications for Use *(Describe)*
The PowerDR Digital X-ray Imaging System is indicated for use as an X-ray imaging modality to acquire, process, display, quality assure and store digital medical X-ray images.
The PowerDR Digital X-ray Imaging System is indicated for use in general radiographic and fluoroscopic examinations of any anatomy for adult, pediatric, and neonatal patients. It is not indicated for use in 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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510(k) Summary 510(k) Number K191504

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Contact/Prepared by: Chen-Tai Ma Ph.D.
Contact Title CEO and President
Date Prepared: August 9, 2019

1. **Identification of the Device:**
   Trade/Device Name: PowerDR™
   Regulation Number: 21 CFR 892.1650
   Regulation Name: Image-intensified fluoroscopic x-ray system
   Regulatory Class: II
   Product Code: JAA, MQB

2. **Equivalent legally marketed device:**
   K130318, Varian Medical Systems, X-Ray Products-InfiMed
   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

3. **Indications for Use (intended use)** The **PowerDR™** Digital X-ray Imaging System is indicated for use as an X-ray imaging modality to acquire, process, display, quality assure and store digital medical X-ray images. The **PowerDR™** Digital X-ray Imaging System is indicated for use in general radiographic and fluoroscopic examinations of any anatomy for adult, pediatric, and neonatal patients. It is not indicated for use in mammography. (Rx Only)

1. **Description of the Device**: The PowerDR™ Console Application is a digital medical X-ray imaging system consisting of an X-Ray detector, computer hardware and the PowerDR™ software. The user supplies the X-Ray generator. The PowerDR™ Console Application is intended to enable a procedure of medical image acquisition, processing, display, quality assurance, and storage. The software interfaces to an X-Ray detector from variety of vendors to acquire raw pixel data. Its image-processing algorithms transform raw pixel data into diagnostic quality images and image sequences to aid the medical professional in diagnosis. For temporary storage, image data can be stored on the local computer. For long term storage, image data can be stored on a portable media device or a remote PACS (Picture Archive and Communication System) server. The PowerDR™ Digital X-ray Imaging System is intended for use in general radiographic and fluoroscopic examinations of any anatomy for adult, pediatric, and neonatal patients. It is not intended for use in mammography. The system can be sold with or without a computer, and with or without a compatible, previously cleared, digital receptor panel. The computer requirements are: Intel Core i5-8500, 6 Core, 9MB Cache, 3.0GHz, 4.1Ghz Turbo w/ HD Graphics 630, Win 10 Pro 64, 8x DVD+/-RW 9.5mm Optical Disk Drive, (2) 3.5 inch 1TB 7200rpm SATA Hard Disk Drives RAID 1, 8GB RAM, Intel Integrated Graphics, 22" display monitor 1920x1080 at 60 Hz. If the customer buys only the software, they are required to install and keep up to date one of the anti-virus programs cited in our User Manual. In addition the device conforms to the applicable provisions EPRC regulations, 21 CFR 1020.30, 1020.31, and 21 CFR 1020.32.

4. **Safety** and **Effectiveness, comparison to predicate device**. The results of image inspection, bench, and test laboratory results indicates that the new device is as safe and effective as the predicate devices. All of the proposed panels have previously received FDA 510(k) clearances.

5. **Substantial Equivalence Chart**

Characteristic	Predicate Device	Proposed Device
Identification	K130318, Varian Medical Systems, X- Ray Products-InfiMed , Trade/Device Name: Nexus DRF Digital X-ray Imaging System	RADinfo SYSTEMS, Digital X-ray Imaging Products, Trade/Device Name: PowerDR™ Console Application
Intended Use:	The InfiMed i5 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 i5 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.	The PowerDR™ Digital X-ray Imaging System is indicated for use to acquire, process, display, quality assure and store digital medical X-ray images. The PowerDR™ Digital X-ray Imaging System is indicated for use in general radiographic and fluoroscopic examinations of any anatomy for adult, pediatric, and neonatal patients. It is not indicated for use in mammography. (similar)
Description	Digital image software application	Same
Where used	Radiology department and medical imaging center use in general radiographic examinations and applications. 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.	Radiology department and medical imaging center use in general radiographic examinations and applications. For the RF/DSA application, the PowerDR™ Digital X-ray Imaging System is intended for use where general fluoroscopy, interventional fluoroscopy or angiography imaging procedures are performed. SAME
Image processing	Image processing algorithms enable the operator to bring out diagnostic details difficult to see using conventional imaging techniques.	The image processing software, used with a cleared DR device, provides diagnostic quality images to aid physicians with diagnosis.
Image Storage	Images can be stored locally for temporary storage.	Same
Image data source	A variety of image receptors from commercially available flat panel detectors.	Same
Configuration	Digital Panel, a connected personal computer, and installed application software.	Same
Primary Digital Panel	Varex/PaxScan 4343CB flat panel detector	Multiple panels supported: Pixium; Careray; Varex/XRPad2. Only FDA cleared panels are supported. See detailed list below.

Characteristic	Predicate Device	Proposed Device
System Software	Installed on a Microsoft Windows PC (Windows 10 64 bit)	Same
Image data format	The input and output image pixel data is the raster data. The photometric representation of the image pixel data is provided.	Same
Image presentation	Enhanced Visualization Processing (EVP)	Same
Application software	Enhanced GUI for easy navigation	Same
Tracking Xray dose	Dose recording from generator	Same
Fluoro image processing	Advanced contrast and edge enhancement	Same
MutiRad image	Support last image hold and review previous frames	Same
Dose and processing Auto optimized	Based on selected Fluoro frames rate and magnification	Same
Quality Assurance	Support various quality assurance tools	Same
DICOM 3.0 Conformance	Yes	Yes
IHE Integration profile	Yes	Yes
Power source (for required computer)	120 VAC	Same
Computer Platform	Windows 10® 64 bit operating system	Same, see computer requirements in description above.

6. **Summary of Bench Testing Conducted:** This is a software product installed on a PC using Windows 10® 64 bit operating system which interfaces with FDA cleared digital x-ray receptor panels. All compatible digital panels have already received FDA clearances. See list below Risk Analysis and software validation was conducted in accordance with FDA guidance documents. All panels had been tested in accordance with the FDA guidance on Solid State Imaging Devices via their previous clearances. We employed these FDA guidance documents in the development of this software product: *Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices Guidance for Industry and FDA Staff MAY 2005; AND Content of Premarket Submissions for Management of Cybersecurity in Medical Devices Guidance for Industry and Food and Drug Administration Staff OCTOBER 2014.* We also employed FDA recommendations in our labeling regarding imaging the pediatric population: *Pediatric Information for X-ray Imaging Device Premarket Notifications Guidance for Industry and Food and Drug Administration Staff, November 2017.* The user manual states: "Use special care when imaging patients outside the typical adult size range. Children are more radiosensitive than adults."

Each available digital receptor panel has undergone a rigorous verification and validation procedure prior to addition to our line-up.

List of Tested Panels

Manufacturer	Model Number	Static/Dynamic Note: All Dynamic panels can take Static Images.	510(k) Number
Thales Pixium	RAD 4343	Static	K133139
Thales Pixium	RAD 4143	Static	K133139
Thales Pixium	RF 4343	Dynamic	K150306
Thales Pixium	3543 EZ	Static	K141440
Thales Pixium	2430 EZ	Static	K141440
Careray	CareView 750C	Static	K163019
Careray	CareView 750Cw	Static	K163019
Careray	CareView 1500 L	Static	K153058
Careray	CareView 1500C	Static	K153058
Careray	CareView 1500Cw	Static	K150929
Careray	CareView 1500P	Static	K162178
Careray	CareView 1800L	Static	K153492
Careray	CareView 1800Cw	Static	K172581
Varex	XRpad2 4336	Dynamic	K161966
Varex	XRpad2 3025	Dynamic	K161942

7. **Summary of Clinical Testing:** Clinical testing was not necessary to establish substantial equivalence. All digital panels employed have received previous FDA clearance.

8. **Conclusion**: After analyzing bench testing and risk analysis and compliance to the DICOM standard, it is the conclusion of Radiology Information Systems, Inc. that the PowerDR™ Digital X-ray Imaging System is as safe and effective as the predicate device, have few technological differences, and has the same indications for use, thus rendering it substantially equivalent to the predicate device.