June 7, 2022

Stephanix Radiological Systems
% Daniel Kamm
Principal Engineer
Kamm & Associates
8870 Ravello Ct
NAPLES FL 34114

Re: K221335
Trade/Device Name: D2RS and D2RS 9090 Digital Dynamic Remote System
Regulation Number: 21 CFR 892.1650
Regulation Name: Image-intensified fluoroscopic x-ray system
Regulatory Class: Class II
Product Code: OWB, JAA, IZI
Dated: May 6, 2022
Received: May 9, 2022

Dear Daniel 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,

Laurel Burk, Ph.D.
Assistant Director
Diagnostic X-ray Systems Team
DHT 8B: Division of Radiological Imaging
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)*
K221335

Device Name
D2RS & D2RS9090 Digital Dynamic Remote System

Indications for Use *(Describe)*
D2RS & D2RS9090 Digital Dynamic Remote System is indicated for use in generating fluoroscopic images of human anatomy for vascular angiography, diagnostic, and interventional procedures. It is also indicated for generating fluoroscopic images of human anatomy for cardiology, diagnostic, and interventional procedures. It is intended to replace fluoroscopic images obtained through image intensifier technology. Not intended for mammography applications.

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 K221335

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D2RS & D2RS9090 Digital Dynamic Remote System

Date Prepared: June 1, 2022
Summary prepared by: Sandie Perret, Quality Manager

1. Trade/Device Name: D2RS & D2RS9090 Digital Dynamic Remote System
   Regulation Number: 21 CFR 892.1650
   Regulation Name: Image-intensified fluoroscopic x-ray system
   Regulatory Class: II
   Product Code: OWB, JAA, IZI

2. Identification of Predicate Device: K213479
   Manufacturer: Stephanix Radiological Systems
   Trade/Device Name: D2RS & D2RS9090 Digital Dynamic Remote System
   Regulation Number: 21 CFR 892.1650
   Regulation Name: Image-intensified fluoroscopic x-ray system
   Regulatory Class: II
   Product Code: OWB, JAA, IZI

3. Reference Device: K202235
   Trade/Device Name: ArtPIX DRF
   Regulation Number: 21 CFR 892.1650
   Regulation Name: Image-intensified fluoroscopic x-ray system
   Regulatory Class: Class II
   Product Code: JAA, MQB

4. Device Description: As compared to the predicate system, we have added a newly compatible Digital Dynamic X-ray receptor panel, model: Pixium RF 4343 FL (Model 4). This panel has already received FDA clearance (reference device above). The original Canon panels remain available. The D2RS & D2RS9090 are direct digital dynamic remote-controlled fluoroscopy and radiography systems equipped with the latest generation of Canon Flat Panel Detector (FPD). The single FPD can perform both fluoroscopy and radiography and is detachable and portable for direct projections to create a unique and highly versatile 3-in-1 imaging solution. The receptor panel directly converts the X-ray images captured by the sensor into a high-resolution digital images. The instrument is suited for use inside a patient environment. This unit converts the X-rays into digital signals. The unit can acquire still and moving images. The system includes a

remotely controlled tilting/elevating table. Panel information: Based on a flat-panel digital detector with the largest field-of-view in the market, the Pixium RF 4343 FL (Model 4) is designed for easy integration in classical R&F tables. It allows manufacturers to offer radiologists an all-digital real-time system, generating high-quality images for both routine dynamic applications and high-end static ones. Digital technology facilitates the work of X-ray technicians and speeds up the process, allowing medical centers to optimize patient throughput. Universal: a single detector for both Radiography or Fluoroscopy. A new tilting table has been introduced (D2RS9090). This new variant of D2RS consists of a modification of the foot of the remote controlled table. Instead of being down the table, this one is now behind. This allows a tilting from -90 to +90° (versus -25 to 90° with previous version) and an elevation from 368 to 1455 cm (versus 640 to 930 cm with previous version). The control console has been updated to a more modern looking design but is functionally identical to the predicate.

5. Indications for Use: The D2RS Digital Dynamic Remote System is indicated for use in generating fluoroscopic images of human anatomy for vascular angiography, diagnostic, and interventional procedures. It is also indicated for generating fluoroscopic images of human anatomy for cardiology, diagnostic, and interventional procedures. It is intended to replace fluoroscopic images obtained through image intensifier technology. Not intended for mammography applications.

6. Technological Characteristics and Substantial Equivalence Comparison with the predicate shows the technological characteristics of the modified devices are equal to or better than the predicate device. Please see the detailed comparison table below. The units are functionally identical. Only the digital panel has changed. The new panel is the Pixium RF 4343 FL (Model 4). A new tilting table has been introduced (D2RS9090). This new variant of D2RS consists of a modification of the foot of the remote controlled table. Instead of being down the table, this one is now behind. This allows a tilting from -90 to +90° (versus -25 to 90° with previous version) and an elevation from 368 to 1455 cm (versus 640 to 930 cm with previous version).

Comparison Table

	D2RS & D2RS9090 Digital Dynamic Remote System K213479	D2RS & D2RS9090 Digital Dynamic Remote System
Indications Statement	D2RS & D2RS9090 Digital Dynamic Remote System is indicated for use in generating fluoroscopic images of human anatomy for vascular angiography, diagnostic, and interventional procedures. It is also indicated for generating fluoroscopic images of human anatomy for cardiology, diagnostic, and interventional procedures. It is intended to replace fluoroscopic images obtained through image intensifier technology. Not intended for mammography applications.	D2RS & D2RS9090 Digital Dynamic Remote System is indicated for use in generating fluoroscopic images of human anatomy for vascular angiography, diagnostic, and interventional procedures. It is also indicated for generating fluoroscopic images of human anatomy for cardiology, diagnostic, and interventional procedures. It is intended to replace fluoroscopic images obtained through image intensifier technology. Not intended for mammography applications. SAME THE INDICATIONS FOR USE HAS NOT CHANGED

	D2RS & D2RS9090 Digital Dynamic Remote System K213479	D2RS & D2RS9090 Digital Dynamic Remote System
Unit Photos		
Control Console		

Digital Panel Comparison Table

	D2RS & D2RS9090 Digital Dynamic Remote System K213479	D2RS & D2RS9090 Digital Dynamic Remote System
Name	Canon CXDI-RF Wireless B1	Pixium RF 4343 FL (Model 4)
Dimension	480 x 460 mm	500 x 490 mm
Useful Area	42 x 43 cm	43 x 43 cm

	D2RS & D2RS9090 Digital Dynamic Remote System K213479	D2RS & D2RS9090 Digital Dynamic Remote System
Photo		
Scintillator	CsI	CsI
Pixel pitch	160 µm	148 µm
Matrix	2592 × 2656 pixels	2874 x 2840 pixels
AD conversion	16 bits	16 bits
DQE	60% (0.5 lp/mm)	73 % typ (0 lp/mm) Similar performance
MTF	38% (2 lp/mm)	35 % typ. (2 lp/mm) Similar performance
Fps Max	30 fps	30 fps
Interface	Ethernet/Wireless WiFi	Ethernet
DICOM 3	YES	YES
Operating temperature	15-40°C	15-40°C

7. Bench/Performance Testing Data: Systems covering all generator/panel combinations were assembled and tested and found to be operating properly. Software was validated according to the FDA Guidance: *Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices (for a moderate level of concern.)* Because the system uses Wi-Fi and Ethernet, we observed the recommendations contained in the FDA Guidance Document: *Content of Premarket Submissions for Management of Cybersecurity in Medical Devices Guidance for Industry and Food and Drug Administration Staff*. For the new digital x-ray panel we provided testing according to the FDA guidance document: *Guidance for the Submission of 510(k)s for Solid State X-ray Imaging Devices Guidance for Industry and Food and Drug Administration Staff.* In addition, we addressed all the items detailed in the FDA publication: "*Pediatric Information for X-ray Imaging Device Premarket Notifications.*"

The X-Ray Units and digital panels have been tested to be in compliance with the following International Standards:

IEC 60601-1:2005 + CORR. 1 (2006) + CORR. 2 (2007), AMD1:2012. Medical electrical equipment Part 1: General requirements for basic safety and essential performance

IEC 60601-1-3:2008, AMD1:2013 for use in conjunction with IEC 60601-1:2005, AMD1:2012 Part 1-3: General Requirements for Radiation Protection in Diagnostic X-Ray Equipment

IEC 60601-1-2:2014 (Edition 4.0) General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - requirements and tests

IEC 60601-1-3:2008+A1:2013 (Edition 2.1) Medical electrical equipment – Part 1-3: General requirements for basic safety and essential performance – Collateral Standard: Radiation protection in diagnostic X-ray equipment

IEC 60601-1-6:2010 + A1:2013 (Edition 3.1) Medical electrical equipment – Part 1-6: General requirements for basic safety and essential performance – Collateral standard: Usability

IEC 60601-2-28:2010 (Edition 2.0) Medical electrical equipment – Part 2-28: Particular requirements for the basic safety and essential performance of X-ray tube assemblies for medical diagnosis

IEC 60601-2-54:2009+A1:2015 (Edition 1.1) Medical electrical equipment – Part 2-54: Particular requirements for the basic safety and essential performance of X-ray equipment for radiography and radioscopy.

IEC 62304:2006 + A1:2016 (Edition 1.1) . Medical device software – Software life-cycle processes
The unit complies with the US Performance Standard for radiographic equipment.

8. Clinical Evaluation. Because the added compatible digital x-ray receptor panel had previously received FDA clearance (reference device) the clinical studies as required by the FDA *Guidance for the Submission of 510(k)s for Solid State X-ray Imaging Devices Guidance for Industry and Food and Drug Administration Staff* were not required.

9. Conclusion: Based on our comparison of technological characteristics and our bench and clinical results, our conclusion is that the modified and updated system is as safe and effective as our predicate device and is therefore substantially equivalent.