Radmedix LLC
℅ Mr. Daniel Kamm
Principal Engineer
Kamm & Associates
8870 Ravello Ct
NAPLES FL 34114

April 13, 2020

Re: K200726
Trade/Device Name: AcuityPDR
Regulation Number: 21 CFR 892.1720
Regulation Name: Mobile x-ray system
Regulatory Class: Class II
Product Code: IZL, MQB, LLZ
Dated: March 17, 2020
Received: March 20, 2020

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)*
K200726

Device Name
AcuityPDR

Indications for Use *(Describe)*
Intended for use by a qualified/trained physician or technician on both adult and pediatric subjects for taking diagnostic x-rays. Not for mammography.
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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.

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"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) Summary K200726

RadmediX, LLC
2510 Lance Rd.
Dayton, OH 45409
Tel 844 723 6334
Registration Number: 3009134655

1. **Administrative Information**
   Reason for Submission: 510(k) Notification for RadmediX AcuityPDR

Submitter:	
Submission contact person:	Gabriel Issa, Director of Equipment
Contact telephone:	844 723 6334
Contact e-mail:	gabe@radmedix.com
Date prepared:	April 9, 2020
Identification:	AcuityPDR
Classification Name:	Mobile X-Ray System
Classification Panel:	Radiology
Classification Regulation:	21 CFR §892.1720
Device Class: Class II	
Product Code: IZL, MQB, LLZ	
Substantially equivalent device:	
Trade Name:	CMDR 2CW
Manufacturer:	MinXray
510(k) #:	K191451
Classification Name:	Mobile X-Ray System
Classification Panel:	Radiology
Classification Regulation:	21 CFR §892.1720
Device Class: Class II	
Product Code: IZL, MQB, LLZ	

2. **Device description:** RadmediX AcuityPDR combines components into a complete mobile x-ray system, including software, a generator/collimator combination, and digital radiography panels. Radmedix combines components from various manufacturers into a complete mobile x-ray system. The customer selects one (or more) of the following digital x-ray receptor panels: DRTech 4343A, (K192400); DRTech 4343W, (K193017); AcuityDR (K171137); AcuityDR 1417 (K162552 EVS 3643, EVS 3643G) or AcuityDR 1717 (K162555 EVS 4343, EVS 4343G). In addition, the customer selects one of three software packages: Accuvue+ (K130883), AccuVueMED, (K152172) or AccuVue (K141440). The generator can be battery operated. A single battery charge produces 200 Exposures at max KV and MAS settings. The battery charger is UL Listed and the internal lithium ion battery is overcharge and overcurrent protected. A typical acquisition computer would be a Lenovo P53S or a Dell Precision 3541.

3. **Indications for Use:** Intended for use by a qualified/trained physician or technician on both adult and pediatric subjects for taking diagnostic x-rays. Not for mammography.

4. **Technological characteristics**: Comparison Table

Comparable Properties	CMDR 2CW, made by MinXray 510(k) #: K191451	AcuityPDR	Comparison Results
Indications for use	Intended for use by a qualified/trained physician or technician on both adult and pediatric subjects for taking diagnostic x-rays. Not for mammography.	Intended for use by a qualified/trained physician or technician on both adult and pediatric subjects for taking diagnostic x-rays. Not for mammography.	Identical
X-ray tube	Toshiba D-124S	TOSHIBA D-125SB 100kV, 40mA	Equivalent Functionality
Peak generator output	2 kW	2 kW	SAME
Tube current range	30 mA±20% at 60kV mA 25 mA±20% at 80kV mA 20 mA±20% at 100kV	40-60kV: 25mA. 61-100kV: 20mA.	Comparable ranges.
Tube voltage adjustable range	40-100 kV, 2kV steps	40-100kV, step value 1kV.	More flexible kV adjustment
mAs range	2.0-150 (steps not specified)	0.4mAs ~ 50mAs, with the range of: 0.40, 0.50, 0.63, 0.80, 1.00, 1.25, 1.6, 2.0, 2.5, 3.2, 4.0, 5.0, 6.3, 8, 10, 12.5, 16, 20, 25, 32, 40, 50.	Comparable adjustability
Collimator	Built in	Built in	Equivalent Functionality
X-ray Generator	Three models, from 100 to 120 kVp maximum	One model, up to 100 kVp	Equivalent Functionality
Digital X-Ray Detectors	K150929 CareView 1500Cw X-ray Flat Panel Detector manufactured by CareRay	DRTech 4343A, (K192400); DRTech 4343W, (K193017); AcuityDR (K171137); AcuityDR 1417 (K162552); AcuityDR 1717 (K162555)	Equivalent Functionality
Operator console	Touch Control or Touch Screen	SAME	Similar Functionality

Comparable Properties	CMDR 2CW, made by MinXray 510(k) #: K191451	AcuityPDR	Comparison Results
Acquisition Software	dicomPACS® DX-R K141440	Customer Selects: AccuVueMED (K152172) AccuVue (K141440) or AccuVue+ (K130883)	Equivalent Functionality Only cleared software is supplied.
Photos			Similar form factors
Power Source	AC LINE, single or three phase depending on the generator	AC Line or rechargeable batteries (Generator only)	SAME.
Standards	60601-1:2005; 60601-1-2:2014 21CFR1020	SAME Generators are TUV Tested AC Line Power Supply is UL Listed See list below.	SAME

5. **Non clinical testing:** Testing was performed successfully according to the following standards:

FDA Recognition Number	Standard Developing Organization	Standard Designation Number And Date	Title Of Standard
19-4	IEC	60601-1:2005/(R)2012 And A1:2012	Medical Electrical Equipment Part 1: General Requirements For Basic Safety And Essential Performance (IEC 60601 1:2005, MOD)
19-1	IEC	60601-1-2:2014	Medical Electrical Equipment Part 12: General Requirements For Basic Safety And Essential Performance Collateral Standard: Electromagnetic Disturbances Requirements And Tests

FDA Recognition Number	Standard Developing Organization	Standard Designation Number And Date	Title Of Standard
12-269	IEC	60601-1-3 Edition 2.1 2013-04	Medical electrical equipment - Part 1-3: General requirements for basic safety and essential performance - Collateral Standard: Radiation protection in diagnostic X-ray equipment
12-296	IEC	60601-2-54 - 2009+AMD1 : 2015+AMD2:2018	Particular Requirements For The Basic Safety And Essential Performance Of X-Ray Equipment for Radiography and Radioscopy
12-238	NEMA	PS 3.1 - 3.20 (2011)	NEMA Digital Imaging and Communications in Medicine (DICOM) Set
N/A	FDA	21CFR1020	Electronic Products; Performance Standard for Diagnostic X-Ray Systems and Their Major Components

All of the components subject to the CDRH performance standard are certified to comply with the standard by their respective manufacturers. We do not supply any non-certified components. Applicable components carry a certification label (UL, ETL, etc.). The digital panel software employed was used unmodified from clearances obtained from FDA. Since multiple configurations are available, our service engineers fully test each new system upon installation at the customer site. In recognition of possible cybersecurity threats to the software, we consulted this guidance: *Content of Premarket Submissions for Management of Cybersecurity in Medical Devices Guidance for Industry and Food and Drug Administration Staff October 2014*. As a result, we updated our own internal standard operating procedures and added cybersecurity precautions to the software users' manuals. The generator User Manual has been updated to add Pediatric Considerations. Each system is tested for proper integration prior to shipment to the customer.

6. Clinical testing. Not required for a determination of substantial equivalence.

7. Substantial Equivalence Discussion.

The RadmediX AcuityPDR performs the same functions using the same technological methods to produce diagnostic x-ray images. In all material aspects, the Visaris and the RadmediX systems are substantially equivalent to each other.

8. Substantial Equivalence Conclusion:

After analyzing bench test results, risk analysis, and clinical evaluation, it is the conclusion of RadmediX LLC that the RadmediX AcuityPDR is as safe and effective as the predicate device, has few technological differences, and has the same indications for use, thus rendering it substantially equivalent to the predicate device.