Radmedix LLC
% Mr. Daniel Kamm
Principal Engineer
Kamm & Associates
8870 Ravello Ct
NAPLES FL 45409

April 30, 2021

Re: K210919
Trade/Device Name: AcuityDRe
Regulation Number: 21 CFR 892.1680
Regulation Name: Stationary x-ray system
Regulatory Class: Class II
Product Code: MQB, LLZ
Dated: March 26, 2021
Received: March 29, 2021

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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K210919

Device Name
AcuityDRe

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.

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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510(k) Summary K210919

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 AcuityDRe

Submitter:

Submission contact person:	Gabriel Issa, Director of Equipment
Contact telephone:	844 723 6334
Contact e-mail:	gabe@radmedix.com
Date prepared:	April 28, 2021

Identification: AcuityDRe
(Three models: AcuityDRe 1417w, AcuityDRe 1717w, AcuityDRe 1717t)
Classification Name: Stationary X-Ray System
Classification Panel: Radiology
Classification Regulation: 21 CFR §892.1680
Device Class: Class II
Product Code: MQB, LLZ

Substantially equivalent device:
Trade Name: Accuvue+
Manufacturer: RadmediX
510(k) #: K201058
Classification Name: Stationary x-ray system
Classification Panel: Radiology
Classification Regulation: 21 CFR §892.1680
Device Class: Class II
Product Code: MQB, LLZ

2. **Device description:** AcuityDRe combines components into a complete digital x-ray system upgrade kit, including software and digital radiography panels. The customer selects one of the following digital x-ray receptor panels: AcuityDRe 1417w, AcuityDRe 1717w, AcuityDRe 1717t. The ”w” indicates wireless wi-fi while the “t” indicates tethered. The indications for use remains unchanged: Intended for use by a qualified/trained physician or technician on both adult and pediatric subjects for taking diagnostic x-rays. Not for mammography. So the only difference between this submission and the predicate submission is the generator/tubestand combination. Each system consists of the following items:
Customer supplies: Diagnostic x-ray generator (HF) Class I Code IZO. + Tubehead: Class I Code ITY + Tube Mount: Class I Code IYB + Attached Collimator, Manual (IZX) Class II 510(k) Exempt
We supply: Digital X-Ray Receptor Panel 892.1680 Class II Code MQB. Digital X-ray Software 892.2050 Class II Code LLZ. The software offered for sale with this system has received previous 510(k) clearance in K201058.

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	Accuvue+, K201058	AcuityDRe	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.	SAME
X-ray Generator	Supplied by User: CPI or Sedecal	Supplied by User: CPI or Sedecal	SAME
Software Control of Technique Factor	Possible for certain CPI or Sedecal Generators (Validated previously). See below.l	Possible for certain CPI or Sedecal Generators (Validated previously). See below.	SAME
Digital X-Ray Detectors	DRTech 4343A, (K192400); DRTech 4343W, (K193017); AcuityDR (K171137); AcuityDR 1417 (K162552); AcuityDR 1717 (K162555)	AcuityDRe 1417w, AcuityDRe 1717w, AcuityDRe 1717t	SAME
Panel Performance	AcuityDR 1417 (K162552);DQE 34.6 % at 1 lp/mm MTF 34 % at 2 lp/mm AcuityDR 1717 (K162555) DQE 23.6 % at 1 lp/mm MTF 34 % at 2.0 lp/mm	AcuityDRe 1417w: DQE @ 1.0 lp/mm: 35%; MTF @ 2.0 lp/mm: 31% AcuityDRe 1717w/1717t: DQE @ 1.0 lp/mm: 42%; MTF @ 2.0 lp/mm: 38%	Almost IDENTICAL
Panel Sizes	AcuityDR 1417 140µm AcuityDR 1717 140µm	AcuityDRe 1417w 148 µm AcuityDRe 1717w 140 µm AcuityDRe 1717t 140 µm	Almost IDENTICAL
Operator console	Windows PC using Windows 10-IoT	SAME	SAME
Acquisition Software	Customer Selects: AccuVue AccuVue+	SAME	SAME.
Power Source	AC Line or rechargeable batteries (wireless models)	AC Line or rechargeable batteries (wireless models)	SAME.
Standards	Same as below	See below	SAME

5. Non clinical testing: Testing was performed 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
12-238	NEMA	PS 3.1 - 3.20 (2011)	NEMA Digital Imaging and Communications in Medicine (DICOM) Set

The digital panel software employed was used unmodified from clearances obtained from FDA. The software has been validated as a control for CPI and Sedecal diagnostic x-ray generators. Compatible CPI generators: CMP 200 Series. Compatible Sedecal generators: SFHR and SHF Series.
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.
In recognition of FDA pediatric concerns, we reviewed the FDA guidance: *Pediatric Information for X-ray Imaging Device Premarket Notifications Guidance for Industry and Food and Drug Administration Staff* and created labeling to comply with this guidance.
In recognition of FDA's concerns about wireless performance we reviewed the FDA guidance: *Radio Frequency Wireless Technology in Medical Devices Guidance for Industry and Food and Drug Administration Staff.* Both the predicate and subject devices use the same wireless technology, standard Wi-Fi using FCC approved off the shelf components.
Since the three new digital receptor panels have not had previous FDA clearance, testing was performed 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*. Clinical image evaluation was performed on the proposed new panels by a Board Certified Radiologist. The images were found to be of excellent quality.
Performance characteristics are as follows:

AcuityDRe 1417w:	DQE @ 1.0 lp/mm: 0.35;	MTF @ 2.0 lp/mm: 0.31
AcuityDRe 1717w:	DQE @ 1.0 lp/mm: 0.42;	MTF @ 2.0 lp/mm: 0.38
AcuityDRe 1717t:	DQE @ 1.0 lp/mm: 0.42;	MTF @ 2.0 lp/mm: 0.38

All proposed compatible generators carry NRTL listing labels, having been tested for safety. Validation of proper generator technique control had been previously performed.
Each system is tested for proper integration prior to shipment to the customer. Since multiple configurations are available (generator and panel models), our service engineers fully test each new system upon installation at the customer site

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

7. Substantial Equivalence Discussion.

When combined with a compatible generator/Tubestand combination the AcuityDRe performs the same functions as the predicate using the same technological methods to produce diagnostic x-ray images. In all material aspects, the Accuvue+ and the AcuityDRe 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 AcuityDRe series of upgrade kits are 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.