



July 12, 2023

Radmedix LLC  
% Daniel Kamm  
Principal Engineer  
Kamm & Associates  
8870 Ravello Ct  
NAPLES, FL 34114

Re: K231709

Trade/Device Name: AcuityDR G4 (AcuityDR 1013 G4, AcuityDR 1417 G4, AcuityDR 1717 G4)  
Regulation Number: 21 CFR 892.1680  
Regulation Name: Stationary x-ray system  
Regulatory Class: Class II  
Product Code: MQB, LLZ  
Dated: June 12, 2023  
Received: June 12, 2023

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](mailto:DICE@fda.hhs.gov)) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

A stylized signature of "Lu Jiang" in a blue, cursive font, overlaid on a light blue, semi-transparent "FDA" logo.

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

## Indications for Use

510(k) Number (if known)  
K231709

Device Name  
AcuityDR G4 (AcuityDR 1013 G4, AcuityDR 1417 G4, AcuityDR 1717 G4)

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.

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**510(k) Summary K231709**



**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 AcuityDR G4

Submitter

Submission contact person: Gabriel Issa, Director of Equipment  
Contact e-mail: gabe@radmedix.com  
Date prepared: June 9, 2023

Identification:

AcuityDR G4 (AcuityDR 1013 G4, AcuityDR 1417 G4, AcuityDR 1717 G4)  
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: AcuityDRe  
Manufacturer: RadmediX  
510(k) #: K210919  
Classification Name: Stationary x-ray system  
Classification Panel: Radiology  
Classification Regulation: 21 CFR §892.1680  
Device Class: Class II  
Product Code: MQB, LLZ

**Reference devices:**

K210314

Trade/Device Name: Mars1717X Wireless Digital Flat Panel Detector  
Regulation Number: 21 CFR 892.1680  
Regulation Name: Stationary x-ray system  
Regulatory Class: Class II  
Product Code: MQB

K210316

Trade/Device Name: Mars 1417X Wireless Digital Flat Panel Detector  
Regulation Number: 21 CFR 892.1680  
Regulation Name: Stationary x-ray system  
Regulatory Class: Class II  
Product Code: MQB

K220668

Trade/Device Name: Wireless Digital Flat Panel Detector  
Regulation Number: 21 CFR 892.1680  
Regulation Name: Stationary X-Ray System  
Regulatory Class: Class II  
Product Code: MQB

**2. Device description:** AcuityDR G4 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: AcuityDR 1013 G4, AcuityDR 1417 G4, AcuityDR 1717 G4. The solid state imaging receptors can be used in wireless or tethered configuration. The indications for use remain 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 available selection of (previously cleared) digital panels. Each system consists of the following items: Customer supplies: Diagnostic x-ray generator (HF) Class I Code IZO. + Tubehead: Class I Code ITV + 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 K210919. We are supplying rebranded versions of the reference devices coupled with the AccuVue software cleared in our predicate K210919.

**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	AcuityDRe, K210919	AcuityDR G4	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.	Possible for certain CPI or Sedecal Generators (Validated previously). See below.	SAME
Digital X-Ray Detectors	AcuityDRe 1417w AcuityDRe 1717w AcuityDRe 1717t	AcuityDR 1013 G4 AcuityDR 1417 G4 AcuityDR 1717 G4	SAME
Panel Performance	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%	AcuityDR 1013 G4: DQE@ 1.0 lp/mm: 51%; MTF @ 2.0 lp/mm: 38%  AcuityDR 1417 G4: DQE@ 1.0 lp/mm: 55.9%; MTF @ 2.0 lp/mm: 40.4%  AcuityDR 1717 G4: DQE@ 1.0 lp/mm: 55.9%; MTF @ 2.0 lp/mm: 40.4%	Similar but better results

Comparable Properties	AcuityDRe, K210919	AcuityDR G4	Comparison Results
Panel Sizes	AcuityDRe 1417w 148 µm AcuityDRe 1717w 140 µm AcuityDRe 1717t 140 µm	AcuityDR 1013 G4 100 µm AcuityDR 1417 G4 100 µm AcuityDR 1717 G4 100 µm	Similar but higher resolution
Operator console	Windows PC using Windows 10-IoT	Windows PC using Windows 10-IoT	SAME.
Acquisition Software	AccuVue	AccuVue	SAME.
Power Source	AC Line or rechargeable batteries (wireless models)	AC Line or rechargeable batteries (all models)	SAME.
Standards	Same as below	Same as 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 606011:2005, MOD)
19-8	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
12-342	NEMA	PS 3.1 - 3.20 (2021e)	NEMA Digital Imaging and Communications in Medicine (DICOM) Set

**6.** The digital panel software employed was used unmodified from clearance obtained from FDA. The software has previously 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. 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 had previous FDA clearance, imaging performance testing had previously been performed. Clinical image evaluation was performed on the proposed panels by a Board Certified Radiologist. The images were found to be of excellent quality.

Performance characteristics are as follows:

AcuityDR 1013 G4: DQE@ 1.0 lp/mm:0.51; MTF @ 2.0 lp/mm: 0.38

AcuityDR 1417 G4: DQE@ 1.0 lp/mm:0.55; MTF @ 2.0 lp/mm: 0.40

AcuityDR 1717 G4 : DQE@ 1.0 lp/mm:0.55; MTF @ 2.0 lp/mm: 0.40

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

- 7. Clinical testing.** Not required for a determination of substantial equivalence.
- 8. Substantial Equivalence Discussion.** When combined with a compatible generator/Tubestand combination the AcuityDR G4 performs the same functions as the predicate using the same technological methods to produce diagnostic x-ray images. In all material aspects, the AcuityDR systems and the AcuityDR G4 systems are substantially equivalent to each other.
- 9. Substantial Equivalence Conclusion:**  
After analyzing bench test results, risk analysis, and clinical evaluation, it is the conclusion of RadmediX LLC that the AcuityDR G4 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.