



October 25, 2023

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

Re: K231995
Trade/Device Name: AcuityUDR
Regulation Number: 21 CFR 892.1680
Regulation Name: Stationary X-Ray System
Regulatory Class: Class II
Product Code: KPR, MQB
Dated: September 24, 2023
Received: September 25, 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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (<https://www.fda.gov/media/99812/download>) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (<https://www.fda.gov/media/99785/download>).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

A stylized signature of 'Lu Jiang' in a cursive font, overlaid on a large, light blue 'FDA' logo.

Lu Jiang, Ph.D.
Assistant Director
Diagnostic X-Ray Systems Team
DHT 8B: Division of Radiological Imaging
Devices and Electronic Products
OHT 8: Office of Radiological Health
Office of Product Evaluation and Quality

Enclosure

Indications for Use

510(k) Number (if known)

K231995

Device Name

AcuityUDR

Indications for Use (Describe)

The purpose of AcuityUDR is to acquire, store, communicate, display and process medical X-ray images. These radiographic systems are intended for use by a qualified/trained physician or technician on both adult and pediatric subjects for taking diagnostic x-rays. Not for mammography, angiography, interventional, or fluoroscopy use.

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 K231995



**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 AcuityUDR, new combination of Exempt and Cleared devices

Submitter:

Submission contact person: Gabriel Issa, Director of Equipment
Contact telephone: 844 723 6334
Contact e-mail: gabe@radmedix.com
Date prepared: September 24, 2023

Identification:

Trade/Device Name: AcuityUDR
Regulation Number: 21 CFR 892.1680
Regulation Name: Stationary x-ray system
Regulatory Class: Class II
Product Code: KPR, MQB

Substantially equivalent device:

K193360
Manufacturer: RadmediX LLC
Trade/Device Name: Acuity SDR Standard, Acuity SDR Plus, Acuity FDR Standard
Regulation Number: 21 CFR 892.1680
Regulation Name: Stationary x-ray system
Regulatory Class: Class II
Product Code: KPR, MQB

Reference devices:

(1) K201043
Manufacturer: iRay Technology Taicang Ltd.
Trade/Device Name: Wireless Digital Flat Panel Detector (Model: Mars1717V-VSI)
Regulation Number: 21 CFR 892.1680
Regulation Name: Stationary x-ray system
Regulatory Class: Class II
Product Code: MQB

(2) K210919
Manufacturer: RadmediX LLC
Trade/Device Name: AcuityDRe
Regulation Number: 21 CFR 892.1680
Product Code: MQB
Subsequent Product Code: LLZ

2. Device description: 21 CFR 807 92 (a) (4)

RadmediX AcuityUDR combines components into a complete stationary x-ray system, including tube stand, tube head, collimator, generator, a digital radiography panel, and image acquisition software.. 21CFR §892.1680 *Identification*. A stationary x-ray system is a permanently installed diagnostic system intended to generate and control x-rays for examination of various anatomical regions. This generic type of device may include signal analysis and display equipment, patient and equipment supports, component parts, and accessories.

The major component combining these into a complete solution is the tube stand. The new tube stand is UL Listed, file number E309191. The tube stands are made to carry the weight of the tube head, collimator, and digital X-ray panels. These tube stands may also have supporting devices such as wall stands, tables, stitching stands, step stools, and chairs. These supporting devices allow for imaging in standing, sitting, and laying positions. The Radmedix Acuity tube stands with supporting devices make a stationary x-ray system allowing for ease of use for the technologist and provides rapid patient care. Similar to the predicate our stationary x-ray system employs a tube stand that is a generic type of device and can use various brands of tube heads, collimators, generators, and digital radiography panels all meeting the cited performance standard.

Radmedix AcuityUDR



Radmedix provides a previously cleared digital x-ray detector. The panel enclosure can support other similarly sized detectors.

The previously cleared software supplied with the system is AccuVue (K210919). This medical software communicates with the digital x-ray detector and allows acquisition and processing of x-ray images. This software complies with DICOM standards and can transmit and receive data with a PACS system. The software is configurable to acquire images from various digital radiography panels.

Available Generators (Unchanged from Predicate)

Summit Models L300, L500, L550, 00210, 02968, 03900, 03901 (40 or 50 kW) or
CPI Model CMP 200 DR (40, 50, 65, or 80 kW)

Collimators (Unchanged from Predicate)

Collimare, LLC CML-150-0001-C, 150kVp Certified Manual Collimator or CML-125-0001-C, 125kVp Certified Manual Collimator

X-Ray Tube Housing: Canon (Unchanged from Predicate)

The purchaser selects one of these:

- Canon E7239FX tube
- Canon E7242FX tube
- Canon E7252FX tube

3. Indications for Use: 21 CFR 807 92 (a) (5)

The purpose of AcuityUDR is to acquire, store, communicate, display and process medical X-ray images. These radiographic systems are intended for use by a qualified/trained physician or technician on both adult and pediatric subjects for taking diagnostic x-rays. Not for mammography, angiography, interventional, or fluoroscopy use.

4. Technological characteristics: 21 CFR 807 92 (a) (6) Comparison Table

Comparable Properties	Acuity (Three models) AcuitySDR Standard; AcuitySDR Plus; AcuityFDR Standard K193360	AcuityUDR	Comparison Results
Indications for use	The purpose of Acuity is to acquire, store, communicate, display and process medical X-ray images. These radiographic systems are intended for use by a qualified/trained physician or technician on both adult and pediatric subjects for taking diagnostic x-rays. Not for mammography, angiography, interventional, or fluoroscopy use.	The purpose of AcuityUDR is to acquire, store, communicate, display and process medical X-ray images. These radiographic systems are intended for use by a qualified/trained physician or technician on both adult and pediatric subjects for taking diagnostic x-rays. Not for mammography, angiography, interventional, or fluoroscopy use.	Identical
Wall stand	Motorized vertical movable wall stand, tiltable tray.	Motorized vertical movable wall stand, tiltable tray.	SAME

Comparable Properties	Acuity (Three models) AcuitySDR Standard; AcuitySDR Plus; AcuityFDR Standard K193360	AcuityUDR	Comparison Results
X-ray tube	150 kVp 0.6/1.2mm focal spots. Canon	SAME	SAME
Collimator	Collimaire collimators, all CFR Certified (510(k) exempt)	SAME	SAME
X-ray Generator	Various Models available: (All HF, All CFR Certified): Summit models from 40 to 50 kW CPI generators up to 80 kW are available optionally. (510(k) exempt)	Various Models available: (All HF, All CFR Certified): Summit models from 40 to 50 kW CPI generators up to 80 kW are available optionally. (510(k) exempt)	SAME
Wireless detector	Enclosure allows for 14" x 17" or 17" x 17" fixed and removable FDA cleared detectors and software.	Includes a 17" x 17" FDA cleared wireless detector, K201043.	Equivalent Functionality
Conventional film/screen systems or CR cassettes	Comes with FDA cleared digital x-ray panels. Conventional film and CR cassettes can still be used	SAME	SAME
Operator console	GUI-based	GUI-based	SAME
Acquisition Software	Customer Selects: AccuVueMED (K152172) AccuVue (K141440)	Accuvue software, most recently cleared in K210919.	Equivalent Functionality Only cleared software is supplied.
Photos	Radmedix AcuitySDR 	Radmedix AcuityUDR 	Similarity is obvious.
Power Source	AC LINE, single or three phase depending on the generator	SAME	SAME.

Comparable Properties	Acuity (Three models) AcuitySDR Standard; AcuitySDR Plus; AcuityFDR Standard K193360	AcuityUDR	Comparison Results
Standards	60601-1:2005; 60601-1-2:2014 60601-2-54 Edition 1.0; PS 3.1 - 3.20 (2011) 21CFR1020	Updated standards	SAME

5. Non clinical testing

Testing on the changed component (the tube stand) was performed successfully according to the following standards:

FDA Recognition Number	Standard Developing Organization	Standard Designation Number And Date	Title Of Standard
19-49	IEC	IEC 60601-1:2005 + A1:2012 + A2:2020	Medical Electrical Equipment Part 1: General Requirements For Basic Safety And Essential Performance
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

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. All X-ray components (generators, tubes, collimators, and applicable accessories) carry an NRTL certification label (UL, ETL, etc.). The software employed was used unmodified from clearances obtained from FDA. 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. Generator User Manuals were previously updated to add Pediatric Considerations.

We also constructed and field tested a complete system and acquired DICOM images from all major body structures, including abdomen, ankle, calcaneus, c-spine ap and c-spine lateral, elbow, foot, knee, hand, l-spine ap and l-spine lateral, shoulder, chest, and skull. All images were of high quality and contrast and clinically acceptable. This testing was performed on an AcuityUDR system equipped with the following components: Stand, (SYFM), a Canon E7242FFX tube head, a Collimaire CML-125, a Summit L550-31 generator, and an iRay Technology Taicang Ltd. digital receptor panel. Each new configuration undergoes a digital image integration protocol and a total system validation protocol prior to shipment to make sure that the configuration works as intended.

6. Clinical testing

Not required for a determination of substantial equivalence.

7. Substantial Equivalence Discussion.

The RadmediX AcuityUDR performs the same functions using the same technological methods to produce diagnostic x-ray images as the predicate. In all material aspects, the two RadmediX systems are substantially equivalent to each other. The flat-panel detectors used with the x-ray system Acuity present comparable or better performance than the predicate detectors.

8. Substantial Equivalence Conclusion:

After analyzing standards test results, risk analysis, and image evaluation (performed on every system after assembly and prior to shipment), it is the conclusion of RadmediX LLC that the RadmediX AcuityUDR System 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.