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

January 2, 2020

Re: K193360
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
Dated: December 2, 2019
Received: December 4, 2019

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)*
K193360

Device Name
Acuity: AcuitySDR Standard; AcuitySDR Plus; AcuityFDR Standard

Indications for Use *(Describe)*
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.

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 K193360

RadmediX, LLC
2510 Lance Rd.
Dayton, OH 45409
Tel 844 723 6334
Registration Number: 3009134655
Radmedix Acuity (AcuitySDR Standard; AcuitySDR Plus; AcuityFDR Standard)

1. Administrative Information

Reason for Submission: 510(k) Notification for RadmediX AcuitySDR Standard; AcuitySDR Plus; AcuityFDR Standard), 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:	December 17, 2019

Identification: AcuitySDR Standard; AcuitySDR Plus; AcuityFDR Standard

Classification Name:	Stationary X-Ray System
Classification Panel:	Radiology
Classification Regulation:	21 CFR §892.1680
Device Class:	Class II
Product Code:	KPR, Secondary: MQB

Substantially equivalent device:

Trade Name:	Visaris Vision® (Vision C, Vision U. Vision V, Vision X)
Manufacturer:	Visaris DOO.
510(k) #:	K160620
Classification Name:	Stationary X-Ray System
Classification Panel:	Radiology
Classification Regulation:	21 CFR §892.1680
Device Class:	Class II
Product Code:	KPR, Secondary: MQB

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

RadmediX Acuity combines components into a complete stationary x-ray system, including software, tube stands, tube heads, collimators, generators, tables, and digital radiography panels.
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.

Radmedix combines components from various manufacturers into a complete stationary x-ray system. The major component combining these into a complete solution is the tube stand. 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 Acuity models:

AcuitySDR Standard;	Straight Arm System Stand: "SYFM SU-2000"	
AcuitySDR Plus;	Straight Arm System Stand with Touchscreen "SYFM SU-2100",	

AcuityFDR Standard	Floor Mounted System "SST-4000"	

Radmedix provides previously cleared digital x-ray detectors. The panel enclosures in our systems are designed around the EVS 3643, EVS 3643G panel cleared under (K151942), and the EVS 4343, EVS 4343G panel cleared under (K142475). Those digital x-ray panels are 14” x 17” and 17” x 17” standard cassette sized digital x-ray detectors. The panel enclosure can support other similarly sized detectors.

The previously cleared software supplied with the system is AccuVueMED (Relabeled version of K152172). 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. The other previously cleared software optionally available package is AccuVue, (Relabeled version of K141440.) The flat-panel detectors used with the x-ray system Acuity present comparable or better performance than the predicate detectors.

The default software AccuVueMED (K152172) is the software normally paired with the default digital panels from DRTECH CORPORATION. Here is a compatibility table:

DRTECH CORPORATION	EVS 3643, EVS 3643G	K162552
DRTECH CORPORATION	EVS 3643	K151942
DRTECH CORPORATION	EVS 4343	K142475
DRTECH CORPORATION	EVS 4343, EVS 4343G	K162555
DRTECH CORPORATION	EVS 2430W, EVS 2430GW	K171137
DRTECH CORPORTATION	EVS 4343W, EVS4343WG, EVS 3643W, EVS 3643WG, EVS 4343WP, EVS 3643WP	K193017

For other optionally available panels the customer would receive the AccuVue software, a relabeled version of K141440. See the table below.

Optionally available panels		
LG Electronics	17HK700G-W	K180332
LG Electronics	14HK701G-W	K182348
LG Electronics	17HK701G-W	K183286
IRay	Mars1717XF-CSI Wireless	K183713
IRay	Mars1717XF-GSI Wireless	K183422
IRay	Mars1417XF-GSI Wireless	K182550
IRay	Mars1417XF-CSI Wireless	K182551
IRay	Mars1417V-PSI Wireless	K161730

Available Generators

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

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

X-Ray Tube Housing: Toshiba

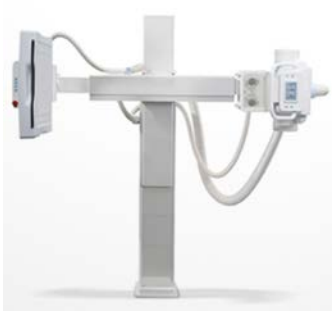
The purchaser selects one of these:
Toshiba E7239FX tube
Toshiba E7242FX tube
Toshiba E7252FX tube

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

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.

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

Comparable Properties	Predicate Device: K160620 Visaris Vision ® (Vision C, Vision U, Vision V, Vision X)	Acuity (Three models) AcuitySDR Standard; AcuitySDR Plus; AcuityFDR Standard	Comparison Results
Indications for use	The purpose of Visaris Vision® 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 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.	Identical
Wall stand	Motorized vertical movable wall stand, tiltable tray.	SAME	Equivalent Functionality
Table	Free-floating and height-adjustable, maximum patient weight 660 lbs., working table height 20-5/16 inch to 37-5/8 inch.	SAME.	Equivalent Functionality
X-ray tube	150 kVp 0.6/1.2mm focal spots. Toshiba	SAME	Equivalent Functionality
Collimator	Ralco Claymount, X-Alliance, or (All CFR Certified) (510(k) exempt)	Collimaire collimators, all CFR Certified (510(k) exempt)	Equivalent Functionality
X-ray Generator	Various Models available: (All HF) Claymount, (up to 63 kW) CPI, (32kW to 100kW) EMD, (45 kW, to 80 kW) POSKOM (32 kW to 50 kW) Sedecal (40, 50, 65, or 80 kW) (All CFR Certified)	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)	Equivalent Functionality
Wireless detector	14” x 17” Uses FDA cleared detector and software. Pixium 3543 EZ C (Other previously cleared models available, see table above)	Optional enclosure allows for 14” x 17” fixed and removable FDA cleared detectors and software.	Equivalent Functionality .
Fixed detector	17”x17”. Uses FDA cleared detector and software. Pixium 4343RC (Other previously cleared models available)	17”x17”. Uses FDA cleared detector and software.	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	Similar Functionality

Comparable Properties	Predicate Device: K160620 Visaris Vision ® (Vision C, Vision U, Vision V, Vision X)	Acuity (Three models) AcuitySDR Standard; AcuitySDR Plus; AcuityFDR Standard	Comparison Results
Operator console	GUI-based	SAME	Similar Functionality
Acquisition Software	Visaris Avanse, K150725,	Customer Selects: AccuVueMED (K152172) AccuVue (K141440)	Equivalent Functionality Only cleared software is supplied.
Photos	Visaris Vision X 	Radmedix AcuitySDR 	Similarity is obvious.
Power Source	AC LINE, single or three phase depending on the generator	SAME	SAME.
Standards	60601-1:2005; 60601-1-2:2014 60601-2-54 Edition 1.0; PS 3.1 - 3.20 (2011) 21CFR1020	SAME Generators are UL Listed	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
19-5	IEC	60601-1:2005	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
12-274	IEC	60601-2-54 Edition 1.0	Medical Electrical Equipment Part 2-54: Particular Requirements For The Basic Safety And Essential Performance Of X¬ Ray Equipment For Radiography And Radioscopy [Including: Technical Corrigendum 1 (2010), Technical Corrigendum 2 (2011)]
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. 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. 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. Generator User Manuals have been 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 AcuitySDR system equipped with the following components: Stand, SYFM SU2100, a Toshiba E7242FXX tube head, a Collimaire CML-125, a Summit L550-31 generator, and a DRTech EVS 4343G 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 Acuity 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. 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 bench test results, risk analysis, and clinical evaluation, it is the conclusion of RadmediX LLC that the RadmediX Systems are as safe and effective as the predicate device, have few technological differences, and has the same indications for use, thus rendering it substantially equivalent to the predicate device.