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

May 6, 2020

Re: K201058
Trade/Device Name: Accuvue+
Regulation Number: 21 CFR 892.1680
Regulation Name: Stationary x-ray system
Regulatory Class: Class II
Product Code: MQB, LLZ
Dated: April 17, 2020
Received: April 21, 2020

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) 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)*
K201058

Device Name
Accuvue+

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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510(k) Summary K201058

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 Accuvue+

Submitter:
Submission contact person: Gabriel Issa, Director of Equipment
Contact telephone: 844 723 6334
Contact e-mail: gabe@radmedix.com
Date prepared: May 4, 2020
Identification: Accuvue+
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: AcuityPDR
Manufacturer: RadmediX
510(k) #: K200726
Classification Name: Moble X-Ray System
Classification Panel: Radiology
Classification Regulation: 21 CFR §892.1720
Device Class: Class II
Product Code: IZL, MQB, LLZ

2. **Device description:** Accuvue+ combines components into a complete digital x-ray system upgrade kit, including software and digital radiography panels. 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). We wish to offer for sale a subset of our recently cleared submission K200726. This in essence would be an upgrade kit. 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. All panels offered for sale with this system have received clearance in K200726.
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 K200726.

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	AcuityPDR K200726	Accuvue+, K201058	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 ELECTRON TUBES & DEVICES CO., LTD D-125SB 100kV, 40mA	Depends on Tube Head/Stand Chosen.	Equivalent Functionality
Collimator	Built in	Depends on Tube Head/Stand Chosen.	Equivalent Functionality
X-ray Generator	One model, up to 100 kVp	Supplied by User: CPI or Sedecal	Equivalent Functionality
Software Control of Technique Factor	Not available	Possible for certain CPI or Sedecal Generators (Validated previously). See below.	Better functionality
Digital X-Ray Detectors	DRTech 4343A, (K192400); DRTech 4343W, (K193017); AcuityDR (K171137); AcuityDR 1417 (K162552); AcuityDR 1717 (K162555)	DRTech 4343A, (K192400); DRTech 4343W, (K193017); AcuityDR (K171137); AcuityDR 1417 (K162552); AcuityDR 1717 (K162555)	SAME
Operator console	Windows PC using Windows 10-IoT	SAME	SAME
Acquisition Software	Customer Selects: AccuVueMED (K152172) AccuVue (K141440) or AccuVue+ (K130883)	AccuVue+ (only)	Equivalent Functionality Only cleared software is supplied.
Power Source	AC Line or rechargeable batteries	AC Line only.	SAME.
Standards	Same as below	See below	SAME

5. Non clinical testing: Testing was performed in previous submssions 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.

Since multiple configurations are available (generator and panel models), 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 User Manual has been updated to add pediatric and cybersecurity considerations. Each system is tested for proper integration prior to shipment to the customer. All proposed compatible generators carry NRTL listing labels, having been tested for safety. Validation of proper generator technique control has been supplied**.**

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

7. Substantial Equivalence Discussion.

When combined with a compatible generator/Tubestand combination the Accuvue+ performs the same functions as the predicate 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 Accuvue+ 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.