Summit Industries LLC
% Daniel Kamm
Principal Engineer
Kamm & Associates
8870 Ravello Ct.
Naples, Florida 34114

February 9, 2018

Re: K173823
Trade/Device Name: Amrad Medical AAU Digital Radiography System; Amrad Medical AAU Plus Digital Radiography System; Amrad Medical DFMT Digital Radiography System; Amrad Medical FMT Digital Radiography System
Regulation Number: 21 CFR 892.1680
Regulation Name: Stationary X-Ray System
Regulatory Class: Class II
Product Code: KPR, MQB
Dated: December 13, 2017
Received: December 18, 2017

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. 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 and Part 809; medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Michael D. O'Hara For

Robert Ochs, Ph.D.
Director
Division of Radiological Health
Office of In Vitro Diagnostics and Radiological Health
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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K173823

Device Name
System #1: Amrad Medical AAU Digital Radiography System; System #2: Amrad Medical AAU Plus Digital Radiography System
System #3: Amrad Medical DFMT Digital Radiography System: System #4: Amrad Medical FMT Digital Radiography System

Indications for Use *(Describe)*
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: Amrad Medical Digital Radiography Systems K173823

Company: Summit Industries, LLC
7555 North Caldwell Avenue,
Niles, Illinois 60714 USA
Phone 773-353-4024 Fax 773-588-3424
Establishment Registration Number: 1450503
Date Prepared: November 13, 2017
Contact Person: Tom Boon, President

This 510(k) summary of safety and effectiveness information is being submitted in accordance with the requirements of 21 CFR §807.92.

1. Device Name and Classification

Trade Names: System #1: Amrad Medical AAU Digital Radiography System
System #2: Amrad Medical AAU Plus Digital Radiography System
System #3: Amrad Medical DFMT Digital Radiography System
System #4: Amrad Medical FMT Digital Radiography System
Regulation Name: Stationary X-Ray System
Classification Panel: Radiology
Classification Regulation: 21 CFR §892.1680
Device Class: Class II
Product Code: KPR

2. Legally Marketed Predicate Device

Trade Names: System #1: Amrad Medical OTS Digital Radiography System
System #2: Amrad Medical DFMTS Digital Radiography System
System #3: Amrad Medical FRS Digital Radiography System
510(k) #: K153119
Regulation Name: Stationary X-Ray System
Classification Panel: Radiology
Classification Regulation: 21 CFR §892.1680
Device Class: Class II
Product Code: KPR

3. Reference Device (Imaging System) The Amrad Systems employ software and digital panels cleared by FDA: THALES/ CMT Medical Technologies Ltd. ArtPix Mobile EZ2GO using Pixium Portable 3543 EZ and 2430 EZ Wireless Detectors
510(k) #: K162224
Classification Name: Stationary X-Ray System
Classification Panel: Radiology
Classification Regulation: 21 CFR §892.1680
Device Class: Class II
Product Code: KPR
Subsequent Product Code: MQB - solid-state X-Ray imager (flat panel / digital imager)

4. Indications for Use: 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.

5. Device Description: The Amrad Systems are permanently-installed diagnostic x-ray systems for general purpose radiographic imaging for use in hospitals, clinics, and medical practices. They are intended to produce diagnostic x-ray images of human anatomy. The Amrad Systems enable radiographic exposures of the whole body including: skull, chest, abdomen, and extremities, and may be used on pediatric, adult, and bariatric patients. Exposures may be taken with the patient sitting, standing, or in the prone position. The resultant images are evaluated by a radiologist within the diagnostic process prior to the development of a treatment plan. It is not intended for fluoroscopy, angiography, or mammography. The Amrad Systems typically include a tube support, x-ray generator, x-ray tube, radiographic table, radiographic wall stand, and collimator. An FDA cleared digital imaging system is included. Below are the specific components in various configurations to form a radiographic system used for general purpose radiographic imaging (see Table 1).

Table 1. Components used Note: X = Included

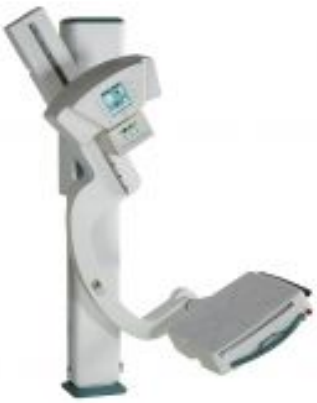
Component Category	Component Description	Component Model.	Mfr,/ Location	Amrad Medical AAU System	Amrad Medical AAU Plus System	Amrad Medical DFMT System	Amrad Medical FMT System
Tubestand	Floor Rail mounted Tube Support	J700 / J700D	Summit USA			X	X
Wallstand	Tilting, Rotational Vertical Wallstand (Floor to wall mounted) with Receptor for Bucky or grid cabinet includes cassette tray, X-ray Grid & may include 1 optional AEC radiation detector	"Millennium" TWBS-TILT	Sedecal Spain			X	X
	Wallstand with Bucky or grid cabinet, includes cassette tray, X-ray grid & may include 1 optional AEC radiation detector (for floor to wall mounting)	J1000	Summit USA			x	x
Combination Tubestand/ Cassette Holder ("C-Arm")	Floor Mounted to wall mounted U-Arm with motorized vertical, rotational and SID movement with receptor for Bucky or grid cabinet, includes cassette tray, removable X-ray grid & may include 1 optional AEC radiation detector	X Plus LP PLUS	Sedecal Spain	x	x		

Component Category	Component Description	Component Model.	Mfr,/ Location	Amrad Medical AAU System	Amrad Medical AAU Plus System	Amrad Medical DFMT System	Amrad Medical FMT System
Radiographic Table	Elevating 4-way Float Top Table And Non-elevating 4 way Float Top Table Includes Reciprocating Bucky or Grid Cabinet, cassette tray, X-Ray Grid & may include optional AEC radiation detector	S222 – Elevating S223 – Non-elevating	Summit USA			X	X
	Mobile Table	ST-1000	SYFM Korea	X	X		
X-ray Generator	X-ray Generator, 80kW, HF, 150kV, (AEC optional)	SHFR 800	Sedecal, Spain	Select one	Select one	Select one	Select one
	X-ray Generator, 65kW, HF, 150kV, (AEC optional)	SHFR 600	Sedecal, Spain				
	X-ray Generator, 50kW, HF, 150kV, (AEC optional)	SHFR 500	Sedecal, Spain				
	X-ray Generator, 40kW, HF, 150kV, (AEC optional)	SHFR 400	Sedecal, Spain				
X-ray Beam Limiting Device	Manual Collimator with LED light source, laser alignment lights & tape measure	R 221 or R225	Ralco Italy	X	X	X	X
Digital Imaging System	Complete Digital Imaging System including Tablet PC (w/ Window OS, monitor, keyboard & mouse), THALES/ CMT Medical Technologies Ltd. K162224 ArtPix Mobile EZ2GO using Pixium Portable 3543 EZ and 2430 EZ Wireless Detectors	Pixium Portable 3543 EZ and 2430 EZ Wireless Detectors	Thales/CMT Medical, France/ Israel	X	X	X	X
X-ray Tube	Toshiba X-ray Tubes, various models	E7242x. E7252X. E7254x. E7255X. E7869X.	Toshiba Electron Tubes & Devices Co. Ltd.	Select one	Select one	Select one	Select one

6. Substantial Equivalence: The Amrad Medical Systems (4 models) are substantially equivalent to the commercially available Amrad Medical OTS, DFMTS, or FRS Digital Radiography Systems K153119 radiographic x-ray system with identical indications for use. The similarities and differences are shown in Table 2, below.

Table 2: Subject and Predicate Device Comparable Properties

Comparable Properties	Amrad Medical OTS, DFMTS, or FRS Digital Radiography Systems K153119	Amrad Medical AAU, AAU Plus, DFMT, or FMT Digital Radiography Systems K173823	Comparison Results
Indications for use	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.	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
Tube crane/Tube stand	Overhead tube crane: OTS	No Overhead tube crane. Only U-Arm, Floor Stand, or Wall/Floor Stand available	Similar Functionality
Wall stand	Manual or Motorized	Manual or Motorized	SAME
Table	Elevating 4-way Float Top Table includes reciprocating bucky, cassette tray, X-ray grid & may include optional AEC measuring detector (for use with OTS & DFMTS Tubestands only) or: Mobile Table (for use with FRS System only)	Elevating 4-way Float Top Table includes reciprocating bucky, cassette tray, X-ray grid & may include optional AEC measuring detector (for use with DFMT & FMT Tubestands only) or: Mobile Table (for use with AAU and AAU Plus)	Same or Similar Functionality
X-ray tube	150 kVp 0.6/1.2mm focal spots	150 kVp 0.6/1.2mm focal spots	Similar Functionality
Collimator	Collimare	Ralco R221 or R225	Similar Functionality
X-ray Generator	CPI Models: 40, 50, 65, or 80 kW	Sedecal Models: 40, 50, 65, or 80 kW	Identical Functionality
Wireless detector	Not applicable	Yes, Cleared Wi-Fi	Greater convenience
Fixed detector	Uses FDA cleared detectors and software: VARIAN PaxScan 4343R and 4336R panels and software cleared in K093066 as well as in K130318.	Uses FDA cleared detectors and software: THALES/ CMT Medical Technologies Ltd. K162224 ArtPix Mobile EZ2GO using Pixium Portable 3543 EZ and 2430 EZ Wireless Detectors	Similar 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.	Comes with FDA cleared digital x-ray panels. Conventional film and CR cassettes can still be used.	Similar Functionality
Operator console	Provided	Same	Similar Functionality

Comparable Properties	Amrad Medical OTS, DFMTS, or FRS Digital Radiography Systems K153119	Amrad Medical AAU, AAU Plus, DFMT, or FMT Digital Radiography Systems K173823	Comparison Results
Photos			Similar Functionality Customer preference is the only difference.
Power Source	AC LINE	SAME	Same.

7. Summary of Technological Characteristics of the Subject Device as Compared with the Predicate Device: As can be seen from the table above, the devices are functionally identical in that they can perform the same kinds of x-ray imaging, but they are different in the mechanical aspects. For example the tube head/collimator combination is ceiling mounted in the predicate whereas the same components are floor mounted in the modified system. In the predicate system, Varian digital panels are employed whereas in the modified system Thales/CMT digital panels are employed. The panels were all previously cleared by FDA in both systems. In all important respects the Amrad Systems are functionally identical and technologically similar in design and composition to the Amrad Medical OTS, DFMTS, or FRS Digital Radiography Systems K153119.

8. Performance Testing. EMC, mechanical safety, and electrical safety were evaluated according to various FDA-recognized consensus standards. In conclusion, the identified risk of EMC, mechanical, and electrical hazards was mitigated and is substantially equivalent to the predicate device in terms of safety and effectiveness. Clinical testing is not required for a determination of substantial equivalence because the imaging components supplied have already received FDA clearance. Furthermore, the intended operators of the Amrad Medical AAU, AAU Plus, DFMT, or FMT Digital Radiography Systems are health care professionals familiar with and responsible for the x-ray examinations being performed. To minimize electrical, mechanical, and radiation hazards, Summit Industries LLC adheres to recognized and established industry practice, and all equipment is subject to final performance testing. All components bear the UL or ETL certification labels.

9. Clinical Evaluation: Since the digital x-ray panels and software had previously received FDA clearance, a clinical study as required by the FDA guidance document was not required. We did collect and evaluate digital images using standardized phantoms.

10. Conclusion as to Substantial Equivalence

The Amrad Medical OTS, DFMTS, or FRS Digital Radiography Systems are intended for the same use as the Amrad predicate. It uses components similar to those cleared for the Amrad Medical OTS, DFMTS, or FRS Digital Radiography Systems K153119 (e.g. tube stand, wall stand, table, x-ray tube, collimator, x-ray generator, operator console). Summit Industries LLC's opinion that the proposed systems are substantially equivalent to the cleared predicate device, the Amrad Medical OTS, DFMTS, or FRS Digital Radiography Systems K153119.