DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

March 14, 2016

Summit Industries LLC
% Mr. Daniel Kamm
Principal Engineer
Kamm & Associates
8870 Ravello Court
NAPLES FL 34114

Re: K153119
Trade/Device Name: Amrad Medical OTS Digital Radiography System
Amrad Medical DFMTS Digital Radiography System
Amrad Medical FRS Digital Radiography System
Regulation Number: 21 CFR 892.1680
Regulation Name: Stationary x-ray system
Regulatory Class: II
Product Code: KPR, MQB
Dated: February 23, 2016
Received: February 26, 2016

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. 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); 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.
If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

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)*
K153119

Device Name
System #1: Amrad Medical OTS Digital Radiography System
System #2: Amrad Medical DFMTS Digital Radiography System
System #3: Amrad Medical FRS 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 K153119

Company: Summit Industries, LLC
2901 W Lawrence Ave.
Chicago, Illinois 60625 USA
Phone 773-353-4024 Fax 773-588-3424
Date Prepared: February 7, 2016

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

1. General Information:

Establishment/Manufacturer/Location of Manufacturing Site:
Summit Industries, LLC
2901 W Lawrence Ave.
Chicago, Illinois 60625 USA
Establishment Registration Number: 1450503

2. Contact Person: Tom Boon, President

3. Device Name and Classification

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

4. Legally Marketed Predicate Device

Trade Name:	Multix Fusion
510(k) #:	K121513
Clearance Date:	August 10, 2012
Classification Name:	Stationary X-Ray System
Classification Panel:	Radiology
Classification Regulation:	21 CFR §892.1680
Device Class:	Class II
Product Code:	KPR

The Amrad Systems employ software and digital panels cleared by FDA: PaxScan 4343R and 4336R panels and software cleared in K093066 as well as in K130318.

5. 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.

6. 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

Component Category	Component Description	Component Model and Serial No.	Mfr, Location	Amrad Medical OTS System	Amrad Medical DFMTS System	Amrad Medical FRS System
Tubestand	Ceiling Mounted Tube Support (OTS), manual motion	J309 & ANA330-0915	Summit Industries, USA	X		
	Floor Mounted Tube Support (DFMTS)	J700 & BFA581-0914	Summit Industries, USA		X	
	Floor Rail mounted Tube Support (FRS)	SST-3001 & SST31405015	SYFM, So. Korea			X
Radiographic 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)	S222 & 41108	Summit Industries, USA	X	X	
	Mobile Table (for use with FRS System only)	ST-1000 & ST11501005	SYFM, So. Korea			X
Wallstand	Wallstand with Reciprocating Bucky, includes cassette tray, X-ray Grid & may include 1 optional AEC radiation detector (for floor to wall mounting)	J1000 (with B066 FDA certified front panel) & 140806	Summit Industries, USA	X	X	
	Tilting, Motorized Vertical Wallstand (Floor mounted) with Image Receptor for Stationary Grid, includes cassette tray (only if portable DR panel is used), X-ray Grid & may include 1 AEC radiation detector	SST-3001 & SST31405015	SYFM, So. Korea & FDA Certified by Summit Industries, USA			X
X-ray Generator	X-ray Generator, 80kW, HF, 150kV, (AEC optional)	CMP200DR	CPI, Canada	Select one	Select one	Select one
	X-ray Generator, 65kW, HF, 150kV, (AEC optional)	CMP200DR	CPI, Canada			
	X-ray Generator, 50kW, HF, 150kV, (AEC optional)	CMP200DR & PD22626H 15	CPI, Canada			
	X-ray Generator, 40kW, HF, 150kV, (AEC optional)	CMP200DR	CPI, Canada			

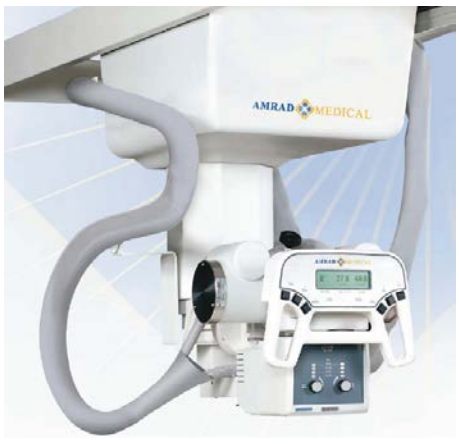
Component Category	Component Description	Component Model and Serial No.	Mfr, Location	Amrad Medical OTS System	Amrad Medical DFMTS System	Amrad Medical FRS System
	X-ray Generator, 40kW, HF, 125kV, (AEC optional)	CMP200DR	CPI, Canada			
X-ray Beam Limiting Device	Manual Collimator with LED light source, laser alignment lights & tape measure	CM-150-24-C-150kVp-01-LED & A03376 & A04056	Collimare, USA	X	X	X
Digital Imaging System	Complete Digital Imaging System including PC (w/ Window OS, monitor, keyboard & mouse), Varian infiMed i5 acquisition/image processing software & either 1 or 2 of the following PaxScan Flat Panel Detectors: 4343R (fixed), 4336R (portable, tethered)	Varian InfiMed i5 Digital Imaging System & i5DR-0714-0044 & U3-T2295244NS01 Uses FDA cleared detectors and software: PaxScan 4343R and 4336R panels and software cleared in K093066 as well as in K130318.	Varian Medical Systems, USA	X	X	X
X-ray Tube	X-ray Tube, 300kHU, 0.6/1.2mm FS, 150kVp	RAD-14 & 35727-T5	Varian Medical Systems, USA	Select one	Select one	Select one

6. Substantial Equivalence: The Amrad Medical Systems (3 models) are substantially equivalent to the commercially available Siemens Multix Fusion (K121513) radiographic x-ray system with similar indications for use. The Multix Fusion was described in premarket notification K121513 which received FDA Clearance on August 10, 2012

Classification Name: Stationary X-Ray System
Classification Panel: Radiology
Classification Regulation: 21 CFR §892.1680
Device Class: Class II
Product Code: 90 KPR

Table 2: Subject and Predicate Device Comparable Properties

Comparable Properties	Predicate Device: Siemens Multix Fusion K12113	Amrad Medical OTS, DFMTS, or FRS Digital Radiography Systems	Comparison Results
Indications for use	The Multix Fusion is a radiographic system used in hospitals, clinics, and medical practices. Multix Fusion enables radiographic exposures of the whole body including: skull, chest, abdomen, and extremities and may be used on pediatric, adult, and bariatric patients. It can also be used for intravenous, small interventions (like biopsy, punctures, etc.) and emergency (trauma, critically ill) applications. Exposures may be taken with the patient sitting, standing, or in the prone position. The Multix Fusion system is not meant for mammography. The Multix Fusion uses a mobile (wired) or portable (wireless) digital detector for generating diagnostic images by converting x-rays into electronic signals. The Multix Fusion is also designed to be used with conventional film/screen or Computed Radiography (CR) cassettes.	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.	Equivalent

Comparable Properties	Predicate Device: Siemens Multix Fusion K12113	Amrad Medical OTS, DFMTS, or FRS Digital Radiography Systems	Comparison Results
Tube crane/Tube stand	Overhead tube crane with manual or automated x-ray tube assembly movement.	Equivalent model: OTS	Similar Functionality
Wall stand	Manual vertical movable wall stand, tiltable tray.	Manual or Motorized	Similar Functionality
Table	Free-floating and height-adjustable, maximum patient weight 660 lbs., working table height 20-5/16 inch to 37-5/8 inch.	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)	Same or Similar Functionality
X-ray tube	150 kVp, 0.6 mm & 1 mm focal spots.	150 kVp 0.6/1.2mm focal spots	Similar Functionality
Collimator	Siemens.	Collimare	Similar Functionality
X-ray Generator	55, 65, or 80 kW	40, 50, 65, or 80 kW	Similar Functionality
Wireless detector	14" x 17"	Not applicable	Not applicable
Fixed detector	14" x 17" or 17" x 17"	SAME. Uses FDA cleared detectors and software: PaxScan 4343R and 4336R panels and software cleared in K093066 as well as in K130318.	Similar Functionality
Conventional film/screen systems or CR cassettes	Film/Screen or CR Cassettes.	Comes with FDA cleared digital x-ray panels. Conventional film and CR cassettes can still be used.	Similar Functionality
Operator console	GUI-based	Same	Similar Functionality
Photos			Similarity is obvious.
Power Source	AC LINE	SAME	Same.

7. Summary of Technological Characteristics of the Subject Device as Compared with the Predicate Device: In all important respects the Amrad Systems are functionally identical and technologically similar in design and composition to the Multix Fusion System.

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 OTS, DFMTS, or FRS 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 Multix Fusion. It uses components similar to those cleared for the Multix Fusion (e.g. tube crane/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 Multix Fusion.