November 26, 2018

Compania Mexicana De Radiologia CGR, S.A. DE C.V.
% Stuart Goldman
Senior Consultant
Emergo Global Consulting, LLC
2500 Bee Cave Road, Bldg. 1, Suite 300
AUSTIN, TEXAS 78746

Re: K182134
Trade/Device Name: ARiX RAD Radiographic System
Regulation Number: 21 CFR 892.1680
Regulation Name: Stationary X-Ray System
Regulatory Class: Class II
Product Code: KPR
Dated: October 11, 2018
Received: October 17, 2018

Dear Stuart Goldman:

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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

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,

Robert A. 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K182134

Device Name
ARiX RAD Radiographic System

Indications for Use *(Describe)*
The ARiX RAD system is a radiographic system used for producing X-ray images of the human body, including all anatomical regions such as the head, thorax, column, abdomen, extremities and internal organs. The system is design to be used with conventional film or CR systems and can be interfaced with a digital detector, but neither the X-Ray detector nor the image acquisition system are part of the ARiX RAD radiographic system. The acquisition system comes as a separate system.

The ARiX RAD system is not intended for use in mammography, fluoroscopy or angiography.

The ARiX RAD system is intended for adults and pediatric patients. The pediatric population is as follows:

- Child (3–12 yrs.), approximately 12 kg (26 lb.) to 51 kg (114 lb.)
- Adolescent (12–21 yrs.), approximately 51 kg (114 lb.) to 80 kg (176 lb.)

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
ARiX RAD Radiographic System
K182134

5.1 Submission Sponsor

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Fraccionamiento Industrial la Noria s/n
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Contact: Tonatiuh Monroy Soberón
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5.2 Submission Correspondent

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Email: Stuart.Goldman@UL.com

5.3 Date Prepared

October 1, 2018

5.4 Device Identification

Trade Name:	ARiX RAD Radiographic System
Common Name:	Radiographic System
Classification Name:	Stationary X-ray
System Regulation Number:	892.1680
Product Code:	KPR, System, X-Ray, Stationary
Class:	Class 2
Classification Panel:	Radiology

5.5 Legally Marketed Predicate Device

Sedecal Millennium Plus (K090279); Manufacturer: Sedecal S.A.

5.6 Indication for Use

The ARiX RAD system is a radiographic system used for producing X-ray images of the human body, including all anatomical regions such as the head, thorax, column, abdomen, extremities and internal organs. The system is designed to be used with conventional film or CR systems and can be interfaced

with a digital detector, but neither the X-Ray detector nor the image acquisition system are part of the ARiX RAD radiographic system. The acquisition system comes as a separate system.

The ARiX RAD system is not intended for use in mammography, fluoroscopy or angiography.

The ARiX RAD system is intended for adults and pediatric patients. The pediatric population is as follows:

- Child (3-12 yrs.), approximately 12 kg (26 lb.) to 51 kg (114 lb.)
- Adolescent (12-21 yrs.), approximately 51 kg (114 lb.) to 80 kg (176 lb.)

5.7 Device Description

The ARiX RAD Radiographic System designed and manufactured by Compañía Mexicana de Radiología (CMR) is a general purpose, computed radiography (CR) X-ray system used for diagnostic imaging (analog radiology) of adults and pediatric patients for taking radiographic exposures of the skull, spinal column, chest, abdomen, extremities, and other body parts. Applications can be performed with the patient sitting, standing, or lying in the prone or supine position. The device is designed to meet the requirements of basic radiology procedures.

The ARiX RAD Radiographic system is capable of interfacing with AeroDR, PaxScan 4336W, Venu1717 detector in trigger mode. However, it is also capable of operating with external triggering devices providing the Hand-switch activation signals and the X-Ray Enable signal of the digital system as an external authorization for the X-Ray emission.

5.8 Substantial Equivalence Discussion

CMR has selected the Sedecal Millennium Plus X-ray system previously cleared by Sedecal S.A. under K090279 as the predicate device for their 510(k) submission. **Table 5-1** compares the ARiX RAD Radiographic System to the predicate device with respect to indications for use, principles of operation, technological characteristics, components/materials, and performance testing. The comparison of the subject device to the predicate device provides more detailed information regarding the basis for the determination of substantial equivalence. The subject device does not raise any new issues of safety or effectiveness based on the similarities to the predicate device.

Table 5-1 – Comparison of Device Characteristics

Attribute	Subject Device	Predicate Device	Comparison
Manufacturer	Compañía Mexicana de Radiología (CMR)	Sedecal S.A.	na
Device Name	ARiX RAD Radiographic System	Sedecal Millennium Plus	na
510(k) #	Pending	K090279	na
Product Code	KPR	KPR	Same
Regulation Number	892.1680	892.1680	Same
Class	II	II	Same
Review Panel	Radiology	Radiology	Same

Attribute	Subject Device	Predicate Device	Comparison
Indications for Use	The ARiX RAD system is a radiographic system used for producing X-ray images of the human body, including all anatomical regions such as the head, thorax, column, abdomen, extremities and internal organs. The system is designed to be used with conventional film or CR systems and can be interfaced with a digital detector, but neither the X-Ray detector nor the image acquisition system are part of the ARiX RAD radiographic system. The acquisition system comes as a separate system. The ARiX RAD system is not intended for use in mammography, fluoroscopy or angiography. The ARiX RAD system is intended for adults and pediatric patients. The pediatric population is as follow: • Child (3-12 yrs.), approximately 12kg (26 lb.) to 51g (114 lb.) • Adolescent (12-21 yrs.), approximately 51kg (114 lb.) to 80kg (176 lb.)	These Digital Radiographic Systems are intended for use by a qualified/trained doctor or technician on both adult and pediatric subjects for taking diagnostic radiographic exposures of the skull, spinal column, chest, abdomen, extremities, and other body parts. Applications can be performed with the patient sitting, standing, or lying in the prone or supine position.	Similar. Both the subject and predicate device have the same intended use as general-purpose diagnostic radiographic systems used for producing X-ray images of the human body, including all anatomical regions such as the head, thorax, column, abdomen, extremities and internal organs, and are indicated for use on adult, adolescent, and pediatric patients.
Technology Overview	General diagnostic X-ray system consisting of a tube-head and collimator assembly, with a generator, generator control, and an X-ray table.	General diagnostic X-ray system consisting of a tube-head and collimator assembly, with a generator, generator control, and an X-ray table.	Same. Both the subject and predicate device are a general type radiographic system used for producing diagnostic X-ray images of the human body, are of similar design and consist of essentially the same types of subcomponents and operate using the same

Attribute	Subject Device	Predicate Device	Comparison
			fundamental scientific technology.
Mechanism of Action	X-ray tube (Dual Focal Spot)	X-ray tube (Dual Focal Spot)	Same
Configuration	Column mount	Column mount	Same
Positioning Controls	Enhanced	Enchased	Same
Collimator	Manual (made by Ralco)	Manual (mad by Ralco)	Same
Anatomical Location	Full body	Full body	Same
Power Supply	220 VCA	220 VCA	Same
Generator	High frequency: 32, 50, 60 and 80 kW (made by CMR)	High frequency: 50 - 80 kW (made by Sedecal)	Similar. The minor difference between the smaller generator size offered by CMR (32 kW) does not raise any new questions of safety and effectiveness between the subject and predicate device, as the subject device has successfully passed electrical safety testing per 60601-1.
Exposure Voltage Ranges for Available Generators	40 - 125 kVp or 40 - 150 kV	40 - 125 kV or 40 - 150 kV	Same
X-ray Current for Available Generators	400 – 800 mA	100 - 300 mA	Similar. The differences in the X-ray current produced by the generators made by CMR do not raise any new questions of safety and effectiveness between the subject and predicate device, as the subject device has successfully passed electrical safety testing per IEC 60601-1, and IEC 60601-2-54.
X-ray Exposure Times	0.001 - 10 s	0.001 - 10 s	Same
Software	Yes	Yes	Same

Attribute	Subject Device	Predicate Device	Comparison
Controlled			
Design and Performance	21 CFR 1020.30 21 CFR 1020.31	21 CFR 1020.30	Same
Electrical Safety and EMC	IEC 60601-1 IEC 60601-1-2 IEC 60601-2-54 (passed TUV)	IEC 60601-1 (passed)	Same

5.9 Non-Clinical Performance Data

As part of demonstrating substantial equivalence of the ARiX RAD Radiographic System to the predicate device, CMR submitted a final finished device for extensive testing to the following voluntary standards:

- IEC 60601-1 (+ ES60601-1), *Medical electrical equipment - Part 1: General Requirements for Basic Safety and Essential Performance* (passed required testing)
- IEC 60601-1-2, *Medical Electrical Equipment - Part 1-2: General Requirements for Basic Safety and Essential Performance – Collateral Standard: Electromagnetic Compatibility - Requirements and Tests* (passed required testing)
- IEC 60601-1-3, *Medical Electrical Equipment - Part. 1: General Requirements for Safety 3. Collateral Standard: General Requirements for Radiation* (passed required testing)
- IEC 60601-1-6, *Medical electrical equipment - Part 1-6: General Requirements for Safety - Collateral Standard: Usability* (passed required testing)
- IEC 60601-2-54, *Medical Electrical Equipment - Part 2- 54: Particular Requirements for the Basic Safety and Essential Performance of X-ray Equipment for Radiography and Radioscopy* (passed required testing)
- ISO 10993-1, *Biological Evaluation of Medical Devices - Part 1: Evaluation and Testing within a Risk Management Process*
    - ISO 10993-5 (cytotoxicity) (passed required testing)
    - ISO 10993-10 (irritation) (passed required testing)
    - ISO 10993-10 (sensitization) (passed required testing)

Additionally, CMR also performed the following internal quality assurance and quality control measures during the design, development and manufacturing stages of their ARiX RAD Radiographic System:

- Risk Analysis (FMEA) per ISO 14971, *Medical Devices - Application of Risk Management to Medical Devices*
- Compliance to 21 CFR Part 1020.30 and 21 CFR Part 1020.31.
- Compliance to the following FDA guidance documents:
    - *Medical Devices and Radiation-Emitting Products, Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices*
    - *Guidance for the Submission of 510(k)s for Solid State X-ray Imaging Devices Pediatric Information for X-ray Imaging Device Premarket Notifications*
    - *Content of Premarket Submissions for Management of Cybersecurity in Medical Devices*

5.10 Clinical Performance Data

Clinical investigations were not required to support the ARiX RAD Radiographic System, as the indications for use are equivalent to those of the predicate device. These types of devices, including the predicate device, have been on the market for many years with proven safety and effectiveness. The non-clinical testing detailed in this submission supports the substantial equivalence of the subject device.

5.11 Statement of Substantial Equivalence

The ARiX RAD Radiographic System has the same intended use as the predicate device. The comparison of technological characteristics, non-clinical performance data, safety testing, biocompatibility testing, and software validation demonstrates that the subject device is as safe and effective as the predicate device. Therefore, the ARiX RAD Radiographic System, as designed and manufactured by Compañía Mexicana de Radiología, is determined to be substantially equivalent to the Sedecal Millennium Plus X-ray system.