Compania Mexicana De Radiologia CGR, S.A. DE C.V. January 28, 2020
% Mr. Stuart R. Goldman
Senior Consultant
Emergo Global Consulting, LLC
2500 Bee Cave Road, Bldg. 1, Suite 300
AUSTIN TX 78746

Re: K193637
Trade/Device Name: MRH ALFA, MRH II & MRH IIE Radiographic Systems
Regulation Number: 21 CFR 892.1680
Regulation Name: Stationary x-ray system
Regulatory Class: Class II
Product Code: KPR
Dated: December 19, 2019
Received: December 27, 2019

Dear Mr. 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/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)*
K193637

Device Name
MRH ALFA, MRH II & MRH IIE Radiographic Systems

Indications for Use *(Describe)*

1. The MRH ALFA 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 MRH ALFA radiographic system. The acquisition system comes as a separate system.

The MRH ALFA system is not intended for use in mammography, fluoroscopy or angiography.
The MRH ALFA system is intended for adults and pediatric patients. The pediatric population is as follow:

- 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.)

2. The MRH II 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 MRH II radiographic system. The acquisition system comes as a separate system.

The MRH II system is not intended for use in mammography, fluoroscopy or angiography.
The MRH II system is intended for adults and pediatric patients. The pediatric population is as follow:

- 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.)

3. The MRH IIE 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 MRH IIE radiographic system. The acquisition system comes as a separate system.

The MRH IIE system is not intended for use in mammography, fluoroscopy or angiography.
The MRH IIE system is intended for adults and pediatric patients. The pediatric population is as follow:

- 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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

Special 510(k) Summary
MRH ALFA, MRH II & MRH IIE Radiographic Systems

1. Submission Sponsor

Compañía Mexicana de Radiología CGR S.A. de C.V.
Fraccionamiento Industrial la Noria s/n
El Marqués, Querétaro
C.P. 76240 México
Phone: (55) 54821300
Contact: Tonatiuh Monroy Soberón
Title: Design Engineer, Regulatory Specialist

2. Submission Correspondent

Emergo Global Consulting, LLC
2500 Bee Cave Road
Building 1, Suite 300
Austin, TX 78746
Office Phone: (512) 327-9997
Email: LST.AUS.ProjectManagement@ul.com
Contact: Stuart R. Goldman
Title: Sr. Consultant RA/QA

3. Date Prepared

December 19, 2019

4. Purpose of the Submission

In this Special 510(k) Compañía Mexicana de Radiología (CMR) is making several minor technological modifications to certain components of their previously cleared ARiX RAD Radiographic System (K182134), the predicate device, that will result in the creation of their new MRH ALFA, MRH II & MRH IIE Radiographic Systems.

5. Device Identification

Trade Name:	MRH ALFA, MRH II & MRH IIE Radiographic Systems
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

6. Legally Marketed Predicate Device

Device name:	ARiX RAD Radiographic System
510(k) No.:	K182134
Manufacturer:	Compañía Mexicana de Radiología CRG S.A. de C.V.

7. Indications for Use

The indications for use on subject devices are identical to the predicate device, the ARiX RAD Radiographic System, as shown below.

The MRH ALFA 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 MRH ALFA radiographic system. The acquisition system comes as a separate system.

The MRH ALFA system is not intended for use in mammography, fluoroscopy or angiography.

The MRH ALFA 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.)

The MRH II 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 MRH II radiographic system. The acquisition system comes as a separate system.

The MRH II system is not intended for use in mammography, fluoroscopy or angiography.

The MRH II 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.)

The MRH IIE 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 MRH IIE radiographic system. The acquisition system comes as a separate system.

The MRH IIE system is not intended for use in mammography, fluoroscopy or angiography.

The MRH IIE 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.)

8. Device Description

The MRH ALFA, MRH II & MRH IIE Radiographic Systems designed and manufactured by CMR are general purpose, computed radiography (CR) X-ray systems 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 devices are designed to meet the requirements of basic radiology procedures and produces a low radiation dose to the patient, while acquiring its images.

9. Device Modifications

The following minor technological modifications have been made to the ARiX RAD Radiographic System (K182134), the predicate device. The minor modifications are being made to several main components of the predicate device to create the subject devices. The minor modifications are: 1) removal of the touch screen functionality from the Control Panel, 2) change the dimensions, load capacity and motorized movement feature of the Powered Table Top, 3) change the height, longitudinal displacement and vertical displacement of the X-ray Tube Stand and 4) change the casing material for the Wall Bucky. In addition, the name of the device is also being changed from the ARiX RAD Radiographic System to the MRH ALFA, MRH II & MRH IIE Radiographic Systems to reflect these different changes for marketing purposes.

10. Substantial Equivalence Comparison

Table 5-1 compares the MRH ALFA, MRH II & MRH IIE Radiographic Systems subject devices to the predicate device ARiX RAD Radiographic System with respect to indications for use, principles of operation, technological characteristics, components/materials, and performance testing. The comparison of the subject devices to the predicate device provides detailed information regarding the basis for the determination of substantial equivalence. The subject devices do not raise any new issues of safety or effectiveness based on the similarities to the predicate device.

Table 5-1 – Substantial Equivalence Comparison of MRH ALFA, MRH II & MRH IIE Radiographic Systems vs. ARiX RAD Radiographic System (K182134)

Attributes	Subject Devices	Predicate Device	Comparison
Device Name	MRH ALFA, MRH II & MRH IIE Radiographic Systems	ARiX RAD Radiographic System	-
Manufacturer	Compañía Mexicana de Radiología (CMR)	Compañía Mexicana de Radiología (CMR)	Same
510(k) #	Pending	K182134	-
Regulatory Information			
Product Code	KPR	KPR	Identical
Regulation	CFR 892.1680	CFR 892.1680	Identical
Regulation Name	Stationary x-ray system	Stationary x-ray system	Identical
Class	II	II	Identical
Review Panel	Radiology	Radiology	Identical
Intended Use	Radiographic system used for producing X-ray images of the human body.	Radiographic system used for producing X-ray images of the human body.	Identical
Indications for Use	The MRH ALFA 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 MRH ALFA radiographic system. The acquisition system comes as a separate system. The MRH ALFA system is not intended for use in mammography, fluoroscopy or angiography. The MRH ALFA 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.) The MRH II system is a radiographic system used for producing X-ray images of the human body, including all	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 12kg (26 lb.) to 51g (114 lb.) • Adolescent (12-21 yrs.), approximately 51kg (114 lb.) to 80kg (176 lb.)	Identical

Attributes	Subject Devices	Predicate Device	Comparison
	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 MRH II radiographic system. The acquisition system comes as a separate system. The MRH II system is not intended for use in mammography, fluoroscopy or angiography. The MRH II 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.) The MRH IIE 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 MRH IIE radiographic system. The acquisition system comes as a separate system. The MRH IIE system is not intended for use in mammography, fluoroscopy or angiography. The MRH IIE 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.)		

Attributes	Subject Devices	Predicate Device	Comparison
	• Adolescent (12-21 yrs.), approximately 51 kg (114 lb.) to 80 kg (176 lb.)		
General Technological Characteristics			
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.	Identical
Mechanism of Action	X-ray tube (Dual Focal Spot)	X-ray tube (Dual Focal Spot)	Identical
Configuration	Column mount	Column mount	Identical
Positioning Controls	Enhanced	Enhanced	Identical
Collimator	Manual (made by Ralco)	Manual (made by Ralco)	Identical
Anatomical Location	Full body	Full body	Identical
Power Supply	220 VCA	220 VCA	Identical
Generator	High frequency: 32, 50, 60 and 80 kW (made by CMR)	High frequency: 32, 50, 60 and 80 kW (made by CMR)	Identical
Exposure Voltage Ranges for Available Generators	40 - 125 kVp or 40 - 150 kVp	40 - 125 kVp or 40 - 150 kV	Identical
X-ray Current for Available Generators	400 – 800 mA	400 – 800 mA	Identical
X-ray Exposure Times	0.001 - 10 s	0.001 - 10 s	Identical
Software Controlled	Yes	Yes	Identical
Safety and Performance Testing Applied			
Design and Performance	21 CFR 1020.30 21 CFR 1020.31	21 CFR 1020.30 21 CFR 1020.31	Identical

Attributes	Subject Devices	Predicate Device	Comparison
Electrical Safety and EMC	IEC 60601-1 IEC 60601-1-2 IEC 60601-1-3 IEC 60601-1-6 IEC 60601-2-54	IEC 60601-1 IEC 60601-1-2 IEC 60601-1-3 IEC 60601-1-6 IEC 60601-2-54	Identical
Biocompatibility	ISO 10993-1 ISO 10993-5 ISO 10993-10	ISO 10993-1 ISO 10993-5 ISO 10993-10	Identical

11. Summary of Safety and Performance Testing

As part of demonstrating substantial equivalence of the MRH ALFA, MRH II & MRH IIE Radiographic Systems to the predicate device, CMR submitted a final finished device for 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 MRH ALFA, MRH II & MRH IIE Radiographic Systems:

- Risk Analysis (FMEA) per ISO 14971, *Medical Devices - Application of Risk Management to Medical Devices*
- Compliance to 21 CFR Part 1020.30 *Diagnostic x-ray systems and their major components* and 21 CFR Part 1020.31 *Radiographic equipment*.
- 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*
    - G*uidance for the Submission of 510(k)s for Solid State X-ray Imaging Devices*
    - *Pediatric Information for X-ray Imaging Device Premarket Notifications*

12. Clinical Testing

Clinical testing on the subject devices have not been performed. 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 devices.

13. Statement of Substantial Equivalence

The MRH ALFA, MRH II & MRH IIE Radiographic Systems have the same intended use and indications for use as the predicate device. The comparison of the mode of operation, technological characteristics and safety and performance testing between the subject devices and the and predicate device demonstrates that the subject devices are as safe and effective as the predicate device. Therefore, the MRH ALFA, MRH II & MRH IIE Radiographic Systems as designed and manufactured by Compañía Mexicana de Radiología are determined to be substantially equivalent to its ARiX RAD Radiographic System (K182134).