SEDECAL SA
% Mr. Daniel Kamm
Principal Engineer
Kamm & Associates
8870 Ravello Ct
NAPLES FL 34114

February 1, 2021

Re: K203537
Trade/Device Name: Proteus XR/f, Models ST and ET, Multirad and Multirad NET Radiographic Systems
Regulation Number: 21 CFR 892.1680
Regulation Name: Stationary x-ray system
Regulatory Class: Class II
Product Code: KPR, MQB
Dated: December 1, 2020
Received: December 3, 2020

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. 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

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)*
K203537

Device Name
Proteus XR/f , Models ST and ET, Multirad and Multirad NET Radiographic Systems

Indications for Use *(Describe)*
These 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.

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: 510(k) Number K203537

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Date Prepared: February 1, 2021
Contact: Mª Luisa Gómez de Agüero, Quality and Regulatory Manager

1) **Identification of the Device:**
Trade/Device Name: Proteus XR/f , Models ST and ET, Multirad and Multirad NET Radiographic Systems
Regulation Number: 21 CFR 892.1680
Regulation Name: Stationary x-ray system
Regulatory Class: II
Product Codes: KPR, MQB.
Common/Usual Name: Diagnostic X-Ray System

2) **Equivalent legally marketed device: K090279**
Trade/Device Name: Sedecal "Millennium Plus Digital Diagnostic X-Ray System"
Regulation Number: 21 CFR 892.1680
Regulation Name: Stationary x-ray system
Regulatory Class: II
Product Codes: KPR, MQB.
Common/Usual Name: Digital Diagnostic X-Ray System

3) Reference device: We employ this cleared device without modification:
Trade/Device Name: Konica Minolta Wireless Detector SKR3000
Submission number: K182688
Regulation Number: 21 CFR 892. 1680
Regulation Name: Stationary x-ray system
Regulatory Class: II
Product Code: MQB

4) **Indications for Use: These 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.**

5) Description of the Device: Proteus Radiographic System, Models XR/f ST and XR/f ET; MULTIRAD and MULTIRAD NET. These radiographic systems are designed for general radiography in hospitals,

clinics, radiology imaging centers and medical practices. It is 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. Patients may be physically abled, disabled, immobilized or in state of a shock. The Radiographic Systems are not intended for mammography applications.
If children are to be examined, they should always be accompanied by an adult.

Radiographic System Proteus XR/f has been interfaced with the Digital Imaging System of Konica Minolta Inc consisting of the image receptor and application for image acquisition (control console & image processing controller). The following table describes all available configurations.

Image receptor, SKR3000 Series included in K182688	**Image acquisition SW included in K182688**
AeroDR 2 1417S (AeroDR P-52)	**CS-7**
AeroDR 3 1417HD (AeroDR P-61)	
AeroDR 3 1717HD (AeroDR P-71)	
AeroDR 3 1012HQ (AeroDR P-81)	

All functions, displays and controls are logically arranged, easily accessible and identified to prevent confusion. Technique factors and functions are selected on the Control Console CS- 7.
The Radiographic Systems Proteus XR/f ST and Proteus XR/f ET units employ a tube stand that supports the X-ray source assembly with the control panel, radiographic table for patient positioning and Wall Stand.

	MULTIRAD	PROTEUS XR/f ST	MULTIRAD NET	PROTEUS XR/f ET
RAD Table	MULT-FWFTTD		NET4000-ST	
Wall Stand	MILL-WBS or MULT-WBS	MILL-WBS	MILL-WBS or MULT-WBS	MILL-WBS
Image System	Not included. Ready to be interfaced with any image acquisition system after performing the task related with the interface.	Konica Minolta (See table above) with CS-7 Software	Not included. Ready to be interfaced with any image acquisition system after performing the task related with the interface.	Konica Minolta (See table above) with CS-7 Software
Tube Stand	MULT-FMTS			
Generator	SHFR Series 50 KW, 65 KW, or 80 KW			
Collimator	Ralco R 225 DHHS			

DAP Meter	VacuDAP-OEM

Tube stand MULT-FMTS includes Control Panel and X-ray source assembly. Column can be moved horizontally with a manual movement trough the rail and rotate on its vertical axis between ± 180 º, with detents at -90º, 0º and 90º position. Dosimeter device and Mechanical tracking Link to center the image receptor of the RAD table with the tube stand are optional items.

The Control Panel is ergonomically built, equipped with logically arranged and easily accessible controls. Column movements are driven by the Control Panel hand-grips. Brakes to allow vertical, horizontal, rotational and transversal travels are released by a slight thumb pressure on the control push-buttons. The control panel includes a SID Display to indicate Source Image Distance and Angle Display to indicate the angle between X-ray source assembly and image receptor.
The system includes a Dose Area Product Measuring System, Model VacuDAP-OEM made by Vacutec.

Substantial Equivalence Chart

Characteristic	K090279 Trade/Device Name: Sedecal "Millennium Plus Digital Diagnostic X-Ray System"	Proteus XR/f , Models ST and ET, Multirad and Multirad NET Radiographic Systems
Indications for Use	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	These 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. (Essentially the same. Wording allows for both digital and traditional versions)
Photo		
Digital Receptor panel/panel sizes	Canon models Model 40G: K023750 Model 40C: K031633 Model 50G: K031447 Model 50C: K060433	Konica Minolta Wireless Detector SKR3000, K182688

Characteristic	K090279 Trade/Device Name: Sedecal "Millennium Plus Digital Diagnostic X-Ray System"	Proteus XR/f , Models ST and ET, Multirad and Multirad NET Radiographic Systems
Panel properties	160 µm, 2208 × 2688 14 x 17 panel size, 12 bit	100 µm/ 200 µm 1,994 x 2,430. 14 x 17 and 17 x 17 panel sizes, 16 bit.
Typ MTF/DQE	0.70 @ 1 lp/mm 0.30 @ 1 lp/mm	0.53 at 1cycle/mm 0.51 at 1 cycle/mm Similar performance
Tube mount	Wall/Floor Suspension	SAME
Image acquisition Software	Canon control software CXDI-NE	Konica Minolta CX-7 provided with panel
Panel Interface	Ethernet	SAME or Wi-Fi wireless
Meets US Performance Standard	YES 21 CFR 1020.30 Diagnostic x-ray systems and their major components. 21 CFR 1020.31 Radiographic equipment.	SAME
X-ray generator	SHF Family Output power: 32, 40 kW, 64 kW, 80 kW.	SHFR Family Output power: 50 KW, 65 KW, 80 KW **SIMILAR RANGE OF OUTPUT POWER**.
	kVp From 40 kV to 125 kV or 150 kV in 1 kV steps**. Accuracy: ±(3% + 1 kVp)**	**kVp** From 40 kV to 150 kV in 1 kV steps Accuracy: ±(3% + 1 kVp)
	mA From 10 mA to 800 mA through the following mA stations: 10, 12.5, 16, 20, 25, 32, 40, 50, 64, 80, 100, 125, 160, 200, 250, 320, 400, 500, 640, 800. (Depending on the Generator model) Accuracy: ±(4% + 1 mA)	**mA** From 10 mA to 800 mA through the following mA stations: 10, 12.5, 16, 20, 25, 32, 40, 50, 65, 80, 100, 125, 160, 200, 250, 320, 400, 500, 650, 800. (Depending on the Generator model) Accuracy: ±(4% + 1 mA)
	mAs Product of mA x Time values from 0.1 mAs to 500 mAs (640 mAs on request) Accuracy: ±(10% + 0.2 mAs	**mAs** Product of mA x Time values from 0.1 mAs to 650 mAs Accuracy: ±(10% + 0.2 mAs
Collimator	Ralco R 302/A DHHS (Manual Collimator)	Ralco R 225 DHHS (Manual Collimator) (updated version of collimator)
Power Source	Mains operated.	SAME

6) **The technological characteristics, including design, materials, composition, and energy source, are substantially the same,** so there are no issues impacting safety and effectiveness.
Safety and Effectiveness, comparison to predicate device. The results of bench testing indicate that the new device is as safe and effective as the predicate devices. Proper system operation is fully verified upon installation. We verified that the modified combination of components worked properly and produced diagnostic quality images as good as our predicate generator/panel combination.

7) **Summary of non-clinical testing**: Systems covering all generator/panel combinations were assembled and tested and found to be operating properly.
Firmware was validated according to the FDA Guidance: *Guidance for the Content of Premarket*

Submissions for Software Contained in Medical Devices Document issued on: May 11, 2005. Because the system uses Wi-Fi and Ethernet, we observed the recommendations contained in the FDA Guidance Document: *Content of Premarket Submissions for Management of Cybersecurity in Medical Devices Guidance for Industry and Food and Drug Administration Staff Document Issued on: October 2, 2014*. Cybersecurity aspects are covered in the digital panel, cleared separately in K182688. The digital panel software employed was already reviewed by FDA in 510(k)s noted in "reference devices" above. Labeling was developed and information provided in accordance with this FDA Guidance Document: *Pediatric Information for X-ray Imaging Device Premarket Notifications, Guidance for Industry and Food and Drug Administration Staff, November 2017*. Labeling also includes reference to the Image Gently website (http://www.imagegently.org/). Because the device contains wireless technology, we consulted *Radio Frequency Wireless Technology in Medical Devices - Guidance for Industry and FDA Staff, AUGUST 2013* and we incorporated those recommendations into our labeling. Wireless aspects pertain to the digital x-ray receptor panel cleared separately in K182688.

The Radiographic System Proteus XR/f has been tested to be in compliance with the following International Standards:

a) 21 CFR 1020.30 Diagnostic x-ray systems and their major components and 21 CFR 1020.31 Radiographic equipment. A product report for the new SHFR generator series was previously submitted. The collimator is certified separately by the manufacturer Ralco.
b) IEC 60601-1:2005+A1:2012 (Edition 3.1) Medical Electrical Equipment, Part 1: General requirements for basic safety and essential performance.
c) IEC 60601-1-2:2014 (Edition 4.0) Medical electrical equipment Collateral Standard: Electromagnetic compatibility Requirements and tests.
d) IEC 60601-1-3:2008+A1:2013 (Edition 2.1) Medical electrical equipment - Part 1-3: General requirements for basic safety and essential performance - Collateral Standard: Radiation protection in diagnostic X-ray equipment
e) IEC 60601-2-54:2009+A1:2015 (Edition 1.2) Particular Requirements For The Basic Safety And Essential Performance Of X-Ray Equipment for Radiography and Radioscopy.

8) **Summary of clinical testing:** Clinical testing was not required to establish substantial equivalence because all digital x-ray receptor panels have had previous FDA clearance.

9) **Conclusion: After analyzing bench and clinical tests, it is the conclusion of Sedecal SA. that the new Radiographic Systems are as safe and effective as the predicate device, have few technological differences, and has the same indications for use, thus rendering it substantially equivalent to the predicate device.**