DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

July 6, 2016

SEDECAL SA
% Daniel Kamm, P.E.
Principal Engineer
Kamm & Associates
8870 Ravello Court
NAPLES FL 34114

Re: K161345
Trade/Device Name: RadPRO® Mobile 40kW; RadPRO® Mobile 40kW FLEXPLUS, Model SM-40HF-B-D-VIR
Regulation Number: 21 CFR 892.1720
Regulation Name: Mobile x-ray system
Regulatory Class: II
Product Code: IZL, MQB
Dated: June 28, 2016
Received: June 30, 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)*
K161345

Device Name
RadPRO® Mobile 40kW; RadPRO® Mobile 40kW FLEXPLUS, Model SM-40HF-B-D-VIR

Indications for Use *(Describe)*
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. Not for mammography.

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)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

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.

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510(k) Summary
510(k) Number K161345

SEDECAL SA
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Date Prepared: June 28, 2016

Contact: Mª Luisa Gómez de Agüero, Quality and Regulatory Manager

1. **Identification of the Device:**
   Trade/Device Name: RadPRO® Mobile 40kW; RadPRO® Mobile 40kW FLEXPLUS, Model SM-40HF-B-D-VIR
   Regulation Number: 21CFR892.1720
   Regulation Name: Mobile X-Ray System
   Regulatory Class: II
   Product Code: IZL and MQB
   Common/Usual Name: Digital Mobile Diagnostic X-Ray System

2. **Equivalent legally marketed device:** K101517
   Trade/Device Name: Sedecal Mobile Digital Diagnostic X-Ray Systems (various models)
   Regulation Number: 21CFR892.1720
   Regulation Name: Mobile X-Ray System
   Regulatory Class: II
   Product Code: IZL and MQB
   Common/Usual Name: Digital Mobile Diagnostic X-Ray System

3. **Indications for Use (intended use)** 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. Not for mammography.

4. **Description of the Device**: RadPRO® Mobile 40kW and RadPRO® Mobile 40kW FLEXPLUS, Model SM-40HF-B-D-VIR are mobile x-ray units that covers all the specific needs of any radiographic examination at the patient's bed, first aid, and emergency, orthopedics, pediatric, and operating theater. These battery or line operated units combine stand-alone feature for exposures with battery assisted motor drive for the greatest ease in imaging. Five different models of digital image acquisition panels are offered: Canon CXDI 401C Wireless, Canon CXDI 701C Wireless, Canon CXDI 801C Wireless. All of the Canon panels and the associated software have been cleared by FDA, (K131106 and K133693) so integration with the mobile system was straightforward. The device complies with the US Federal Safety Performance Standard and is UL listed. The key differences between the modified device and the predicate device are as follows:
   4.1. The FLEXPLUS version has a telescoping Tubestand which enhances visibility while transporting the unit.
   4.2. We are offering updated versions of the Canon Digital X-Ray Panels, as listed above and shown in the comparison table below.

4.3. We have added a second personal computer board which permits “Enhanced Work Flow” capability. The second, independent computer is configured to run a second, independent software system, (to be supplied by the user) to allow a user to toggle to a Work Flow environment for ease-of-use in mobile X-ray systems. This second computer is configured to be a "slave" to the X-ray system software, including both Canon CXDI and Sedecal Integration software (e.g., the second computer is turned on and off by the X-ray System's power status). The second computer and its Windows environment is specified with sufficient computing requirements to enable third-party client software to be installed that could include RIS, QC and PACS communications.

4.4. We have added what we call a “DAS”, a distributed antenna system that enhances the detectability of the accompanying detectors, both in range and sensitivity, also increasing the overall wireless sensitivity by utilizing 4 sector antennas.

4.5. We have updated the User Manual to reflect the changes made to the device.

5. **Safety and Effectiveness, comparison to predicate device.** Bench, test laboratory results, and clinical image comparisons indicate that the new device is as safe and effective as the predicate devices. All digital panels have previous FDA clearance and are provided unmodified**.**

6. **Substantial Equivalence Chart**

Characteristic	**Sedecal Easy Moving Digital K101517**	**RadPRO® Mobile 40kW; RadPRO® Mobile 40kW FLEXPLUS, Model SM-40HF-B-D-VIR K161345**
Intended Use:	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.	SAME, adding FDA requested language: Not for mammography.
Configuration	Battery or line operated mobile	SAME, now with telescopic tube mount (FLEX PLUS) (see photo below)
Performance Standard	21 CFR 1020.30	SAME
Generator	High frequency made by Sedecal	SAME
Generator power level	Four available power levels: 20 KW, 32 KW, 40 KW, 50 KW	40 kW (One power level)
Collimator	Ralco R221 DHHS Manual Collimator	SAME

Characteristic	Sedecal Easy Moving Digital K101517	RadPRO® Mobile 40kW; RadPRO® Mobile 40kW FLEXPLUS, Model SM-40HF-B-D-VIR K161345
Image acquisition	Trixell 3543pR: (Wireless) Pixel size 144 µm/2372 x 3000 pixels or Varian 4336R Pixel size 139 µm/3072 x 2560 pixels	Canon CXDI 401C Wireless (CSI) K133693 Pixel size: 125 µm 3320 × 3408 pixels Canon CXDI 701C Wireless (CSI) K131106 Pixel size: 125 µm 2800 × 3408 pixels Pixel size: 125 µm 2800 × 3408 pixels Canon CXDI 801C Wireless (CSI) K131106 Pixel size: 125 µm 2800 × 2192 pixels
Software	dicomPACS®DXR	Canon control software CXDI-NE
Connection	Ethernet or Wireless Wi-Fi	SAME
DICOM	YES	YES
Workflow	Not applicable	Enhanced Work Flow via second PC.
Power Source	AC Line or Rechargeable Battery	SAME
Electrical safety and EMC	Electrical Safety per IEC-60601. UL listed; EMC per IEC-60601-1-2; IEC 60601-1-3 Radiation protection in diagnostic X-ray equipment IEC 60601-2-54 Particular Requirements For The Basic Safety And Essential Performance Of X-Ray Equipment for Radiography and Radioscopy	SAME
Standards (Other than Electrical and EMC)	Wi-Fi 802.11b/g	Wi-Fi 802.11b/g and: FCC Rules and Regulations 47 CFR Chapter I Part 15 Subpart B; Part 18 Subpart C ICES-003 ISSUE 5 (2012) & ICES-001 ISSUE 4 (2014) & ANSI C63.4-2009.
Wi-Fi communication with detectors	One single antenna	“DAS” distributed Wi-Fi antenna system

Characteristic	Sedecal Easy Moving Digital K101517	RadPRO® Mobile 40kW; RadPRO® Mobile 40kW FLEXPLUS, Model SM-40HF-B-D-VIR K161345
Photos		RadPRO® Mobile  RadPRO® Mobile Flex Plus 

7. Summary of Laboratory Testing and Bench Testing: Laboratory testing included performance testing to the DHHS Radiation Safety Performance Standard, Electrical Safety per IEC-60601. EMC per IEC-60601-1-2; IEC 60601-1-3 Radiation protection in diagnostic X-ray equipment, IEC 60601-2-54 Particular Requirements For The Basic Safety And Essential Performance Of X-Ray Equipment for Radiography and Radioscopy, and FCC Parts 15 and 18. Software integration testing (enhanced workflow) was documented and a detailed risk analysis was performed. Test images were obtained to confirm total system functionality. Every unit manufactured undergoes thorough performance testing which includes visual and configuration testing, leakage testing, hi-pot testing, power supply testing, (batteries, etc.), generator controls (voltage, current, timing), and image acquisition. Additional Wi-Fi testing was done to verify the functionality of internal Wi-Fi antennas. Mechanical testing of the new telescoping Tubestand was performed.

8. Summary of Clinical Testing: Not required because all of the proposed digital panels have prior FDA clearance. Sample images were verified by a Board Certified Radiologist.

9. Conclusion After analyzing bench and laboratory testing to applicable standards, it is the conclusion of Sedecal SA that the modified Sedecal Mobile X-Ray Systems are as safe and effective as the predicate devices, have few technological differences, and has no new indications for use, thus rendering them substantially equivalent to the predicate devices.