August 21, 2023

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

Re: K232185
Trade/Device Name: SM-IV
Regulation Number: 21 CFR 892.1720
Regulation Name: Mobile x-ray system
Regulatory Class: Class II
Product Code: IZL
Dated: July 17, 2023
Received: July 24, 2023

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,

Lu Jiang

Lu Jiang, Ph.D.
Assistant Director
Diagnostic X-Ray Systems Team
DHT8B: Division of Radiological Imaging
Devices and Electronic Products
OHT8: Office of 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: 06/30/2023
See PRA Statement below.

Submission Number *(if known)*

K232185

Device Name

SM-IV

Indications for Use *(Describe)*

This is a mobile diagnostic x-ray system 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)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510(k) Summary: 510(k) Number K232185

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Date Prepared: August 4, 2023
Contact: Mª Luisa Gómez de Agüero, Quality and Regulatory Manager

1) **Identification of the Device:**
   Trade/Device Name: SM-IV
   Regulation Number: 21 CFR 892.1720
   Regulation Name: Mobile x-ray system
   Regulatory Class: II
   Product Codes: IZL.
   Common/Usual Name: Mobile Diagnostic X-Ray System

2) **Equivalent legally marketed device**: **K212291**
   Trade/Device Name: PHOENIX
   Regulation Number: 21 CFR 892.1720
   Regulation Name: Mobile x-ray system
   Regulatory Class: II
   Product Codes: IZL, MQB.
   Common/Usual Name: Digital Mobile Diagnostic X-Ray System

3) **Indications for Use:** This is a mobile diagnostic x-ray system 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**: This is a battery powered mobile diagnostic x-ray system which is provided without the digital x-ray acquisition systems used on our predicate model. The unit is provided with Lithium batteries to supply both X-ray generator for X-ray exposures and motors for movements instead of the Sealed Lead Acid batteries of the predicate model. This system has been made lighter and therefore more maneuverable. Lithium batteries provide a much lower charging time and more autonomy in standby. The indication for use remains the same as the predicate. The x-ray generator has been adapted to the new power supply based on Lithium batteries. The collimator is the same. The main features of this equipment are:
   a) A solid and ergonomic design. Easy operation, safety and precision of all positioning movements relative to the position of the patient.
   b) Standard electrical outlet operation with single-phase lines at 100 -- 240 V~. Automatic line voltage compensation.

c) Head-Assembly rotation in relation to its transversal axis (±180°) and horizontal axis (120°). Collimator rotation in relation to its vertical axis (±90°).
d) Controls for lock release of Rotating Column and Telescopic Arm.
e) Column rotation in relation to its vertical axis (±317°), telescopic and vertical motion of the Arm.
f) X-ray Handswitch for X-ray exposures and Collimator Light.
g) Infrared Remote X-ray Handswitch (optional) for X-ray exposures and Collimator Light.
h) Dosimetry (optional):
    i) DAP reading with an Ion Chamber.
    ii) Calculated DAP (eDAP).
i) Manual Collimation.
j) Tube protection circuitry prolongs Tube life and increases system performance.
k) Equipped with closed loop control of X-ray Tube current, kVp and filaments, which minimize potential errors and the need for readjustments.

There is no imaging hardware or software supplied with the unit. That is the responsibility of the purchaser. The x-ray flat panel detectors (an integral part of a complete diagnostic system) are not part of the SM-IV device and must me provided separately by the user.

5) Substantial Equivalence Chart

Characteristic	Predicate: K212291 PHOENIX	**SM-IV**
Indications for Use:	This is a digital mobile diagnostic x-ray system 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	This is a mobile diagnostic x-ray system 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. (Same)
Configuration	Mobile System with digital x-ray panel and image acquisition computer	SAME but no image acquisition software or hardware s supplied.
X-ray Generator(s)	20, 32, 40 kW and 50 kW Monoblock generator kV range: from 40 kV to 150 kV mA range: 10 mA – 630mA mAs range: from 0.1 mAs to 500 mAs	20, 32, 40 kW and 50 kW Monoblock generator kV range: from 40 kV to 150 kV mA range: 10 mA – 630mA mAs range: from 0.1 mAs to 500 mAs (Same)
Collimator	Ralco R108F	Same

Characteristic	Predicate: K212291 PHOENIX	**SM-IV**
Photos		
Touch screen control	Yes, 19”	19” or 21’5”
Motorized movement	Included	SAME
Meets US Performance Standard	YES 21 CFR 1020.30	SAME
Power Source	Universal power supply, from 100 V~ to 240 V~. 1 phase	SAME
Type of Batteries	Sealed Lead batteries	Lithium batteries
Standby autonomy	The Mobile Unit in Stand-Alone (disconnected from the mains) will be 100% discharged from full charge in approximately: 11 hours	The Mobile Unit in Stand-Alone (disconnected from the mains) will be 100% discharged from full charge in approximately: **17 hours.**
Charging time	The required time for the Batteries to be 100% charged is approximately: 8 hours.	The required time for the Battery to be 100% charged is approximately: 4 hours.
Imaging Software	Konica-Minolta control software CS-7 (K151465 or K172793) OR Konica-Minolta control software Ultra.	Not included
Digital detector Interface	Ethernet or Wi-Fi wireless	Not applicable
Size	122 x 540 x 223 cm	122 x 540 x 222 cm
Weight	520 kg	450 kg.
Digital Detectors	AeroDR Series	Not included.

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 device. Here is a summary of the changes we made to the device: The battery technology has changed from sealed lead acid to lithium and the digital imaging components have been removed to allow for various other previously cleared digital receptor panels to be installed by trained service technicians.

7) **Summary of non-clinical testing**: A system was assembled and tested and found to be operating properly. Firmware was essentially unchanged except a small adaptation required by lithium batteries. Because the system has an Ethernet interface, 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.* The internal computer is available for the installation of user supplied imaging software.

   The SM-IV Battery Mobile X-Ray Unit has been tested to be in compliance with the following International Standards:

   IEC 60601-1 Edition 3.2 2020-08 CONSOLIDATED VERSION FDA #19-49
   IEC 60601-1-2:2020 + A1:2020 (Edition 4.1) FDA #19-36
   IEC TR 60601-4-2 (Edition 1.0 2016-05) FDA #19-19
   IEC 60601-1-3:2008+A1:2013 + A2: 2021(Edition 2.1) FDA 12-336
   IEC 60601-2-54:2009+A1:2015 + A2:2018 (Edition 1.2) FDA 12-317
   IEC 60601-2-28:2017 (Edition 3.0) FDA 12-309
   IEC 60601-1-6:2010 + A1:2013 + A2: 2020 (Edition 3.2) FDA 5-132
   IEC 62304:2006 + A1:2015 (Edition 1.1) FDA 13-79

8) Summary of clinical testing: Clinical testing was not required to establish substantial equivalence.

9) Conclusion: After analyzing bench and non-clinical tests, it is the conclusion of Sedecal SA. that the SM-IV Diagnostic Mobile X-Ray System is as safe and effective as the predicate device, has few technological differences, and has the same indications for use, thus rendering it substantially equivalent to the predicate device.