September 14, 2021

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

Re: K212291
Trade/Device Name: PHOENIX
Regulation Number: 21 CFR 892.1720
Regulation Name: Mobile x-ray system
Regulatory Class: Class II
Product Code: IZL, MQB
Dated: July 20, 2021
Received: July 22, 2021

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

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.

510(k) Number *(if known)*
K212291

Device Name
PHOENIX

Indications for Use *(Describe)*

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.

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."

510(k) Summary: 510(k) Number K212291

SEDECAL SA
C/ Pelaya, 9 – 13, Pol. Ind. Río de Janeiro
28110 Algete, Madrid España (Spain)
Tel.- +34 91 6280544
Fax.- +34 91 6280574
Date Prepared: August 7, 2021
Contact: Mª Luisa Gómez de Agüero, Quality and Regulatory Manager

1) **Identification of the Device:**
   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

2) **Equivalent legally marketed device**: **K192011**
   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) **Reference devices:** We employ these cleared devices without modification:
   Trade/Device Name: (K151465 and K172793) Konica-Minolta Digital X-ray Panels
   AeroDR P-51 with CS-7 (K151465)
   AeroDR P-52 with CS-7 (K151465)
   AeroDR P-61 with CS-7 (K172793)
   AeroDR P-71 with CS-7 (K172793)
   AeroDR P-81 with CS-7 (K172793)
   Regulation Number: 21 CFR 892. 1680
   Regulation Name: Stationary x-ray system
   Regulatory Class: II
   Product Code: MQB

4) **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.

5) **Description of the Device**: This is a new type of our previous predicate mobile PhoeniX. The predicate PhoeniX mobile is interfaced with Konica – Minolta Digital X-ray panels and CS-7 or Ultra software image acquisition. Phoenix mobile systems will be marketed in the USA by KONICA MINOLTA. Models with the CS-7 Software will be marketed as AeroDR Tran-X Models with the Ultra Software will be marketed as mKDR II. The compatible digital receptor panels are the same for either model. The CS-7 software was cleared under K151465/K172793, while the Ultra software is new. The CS-7 is a DIRECT DIGITIZER used with an image diagnosis device, medical imaging device and image storage device connected via the network. This device digitally processes patient images collected by the medical imaging device to provide image and patient information. By contrast the Ultra-DR software is designed as an exam-based modality image acquisition tool. Ultra-DR software and its accompanying Universal Acquisition Interface (UAI) were developed to be acquisition device independent. Basic Features of the software include Modality Worklist Management (MWM) / Modality Worklist (MWL) support, DICOM Send, CD Burn, DICOM Print, and Exam Procedure Mapping. Ultra Software is designed to increase patient throughput while minimizing data input errors. Ultra is made up of multiple components that increase efficiency while minimizing errors. The main components of Ultra are the Worklist, Acquisition Interface and Configuration Utility. These components combine to create a Stable, Powerful, and Customizable Image capture system. The intuitive graphical user interface is designed to improve Radiology, Technologist accuracy, and image quality. Worklist and Exam screens were developed to allow site specific customizations to seamlessly integrate into existing practice workflows.
We decided to continue to offer the CS-7 package as a lower cost option for those users who do not need the enhances features of the Ultra software.
Both software packages are of Moderate level of concern. As noted in section 3, above, reference devices: All digital flat panel detectors have received FDA clearance.

6) Substantial Equivalence Chart

Characteristic	Predicate: K192011 PHOENIX	PHOENIX
Indications for 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.	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. (Same, includes device description as requested by FDA)
Configuration	Mobile System with digital x-ray panel and image acquisition computer	SAME
X-ray Generator(s)	kW rating: 20 kW, 32 kW, 40 kW and 50 kW. kV range: from 40 kV to 150 kV in 1 kV steps. mA range: from 10 mA to 630 mA / 640 mA / 650 mA.	SAME
Collimator	Ralco R108F	Ralco R108F

Characteristic	Predicate: K192011 PHOENIX	PHOENIX
Photos		
Meets US Performance Standard	YES 21 CFR 1020.30	SAME
Power Source	Universal power supply, from 100 V~ to 240 V~. 1 phase, 1.2 kVA	SAME
Software	Canon control software CXDI-NE	Konica-Minolta control software CS-7 (K151465 or K172793) OR Konica-Minolta control software Ultra.
Panel Interface	Ethernet or Wi-Fi wireless	SAME
DETECTOR TECHNOLOGICAL COMPARISONS		
Image area sizes	CANON CXDI-401C 16”x 17” CANON CXDI-701C 14” x 17” CANON CXDI-801C 11” x 14” CANON CXDI-710C 14” x 17” CANON CXDI-810C 14” x 11” CANON CXDI-410C 17” x 17”	AeroDR P-51 14” x 17” AeroDR P-52 14” x 17” AeroDR P-61 14” x 17” AeroDR P-71 17” x 17” AeroDR P-81 10” x 12” Similar range of sizes (All previously cleared)
Pixel sizes	CANON CXDI-401C 125 µm CANON CXDI-701C 125 µm CANON CXDI-801C 125 µm CANON CXDI-710C 125 µm CANON CXDI-810C 125 µm CANON CXDI-410C 125 µm	AeroDR P-51 175 µm AeroDR P-52 175 µm AeroDR P-61 100/200 µm AeroDR P-71 100/200 µm AeroDR P-81 100/200 µm Similar pixel sizes (All previously cleared)

Characteristic	Predicate: K192011 PHOENIX	PHOENIX
Resolutions	CANON CXDI-401C 3320 × 3408 pixels CANON CXDI-701C 2800 × 3408 pixels CANON CXDI-801C 2800 × 2192 pixels CANON CXDI-710C 2800 × 3408 pixels CANON CXDI-810C 2800 × 2192 pixels CANON CXDI-410C 3320 × 3408 pixels	AeroDR P-51 1994 x 2430 pixels AeroDR P-52 1994 x 2430 pixels AeroDR P-61 3488 × 4256 pixels AeroDR P-71 4248 × 4248 pixels AeroDR P-81 2456 × 2968 pixels
MTF	CANON CXDI-401C 0.35 @ 2cy/mm CANON CXDI-701C 0.35 @ 2cy/mm CANON CXDI-801C 0.35 @ 2cy/mm CANON CXDI-710C 0.35 @ 2cy/mm CANON CXDI-810C 0.35 @ 2cy/mm CANON CXDI-410C 0.35 @ 2cy/mm	AeroDR P-51 0.30 @ 2cy/mm AeroDR P-52 0.30 @ 2cy/mm AeroDR P-61 0.30 @ 2cy/mm AeroDR P-71 0.30 @ 2cy/mm AeroDR P-81 0.30 @ 2cy/mm
DQE	CANON CXDI-401C 0.6 @ 0 lp/mm CANON CXDI-701C 0.6 @ 0 lp/mm CANON CXDI-801C 0.6 @ 0 lp/mm CANON CXDI-710C 0.6 @ 0 lp/mm CANON CXDI-810C 0.6 @ 0 lp/mm CANON CXDI-410C 0.6 @ 0 lp/mm	AeroDR P-51 0.62 @ 0 lp/mm AeroDR P-52 0.62 @ 0 lp/mm AeroDR P-61 0.56 @ 1 lp/mm AeroDR P-71 0.56 @ 1 lp/mm AeroDR P-81 0.56 @ 1 ip/mm
Software	Canon control software CXDI-NE	Konica-Minolta control software CS-7 (K151465 or K172793) OR Konica-Minolta control software Ultra.
Panel Interface	Ethernet or Wi-Fi wireless	SAME

7) **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 devices are 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. Here is a summary of the changes we made to the device: The flat-panel detectors were replaced with the Aero-DR series and the software was changed from the Canon control software CXDI-NE to the Konica-Minolta control software CS-7 (K151465 or K172793) OR Konica-Minolta control software Ultra.

8) **Summary of non-clinical testing**: Systems covering all generator/panel combinations were assembled and tested and found to be operating properly.
Firmware was unchanged. New image acquisition software (Utra) was validated according to the FDA Guidance: *Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices .*
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.* The CS-7 digital panel software employed was already reviewed by FDA in K172793.

The PHOENIX Battery Mobile X-Ray Units have been tested to be in compliance with the following International Standards:

a) IEC 60601-1:2005+A1:2012 (Edition 3.1)
b) IEC 60601-1-2:2014 (Edition 4.0)
c) IEC 60601-1-3:2008+A1:2013 (Edition 2.1)
d) IEC 60601-2-54:2009+A1:2015 (Edition 1.1)
e) IEC 60601-2-28:2010 (Edition 3.0)
f) IEC 60601-1-6:2010 + A1:2013 (Edition 3.1)
g) IEC 62304:2006 + A1:2016 (Edition 1.1)

9) **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.

10) **Conclusion: After analyzing bench and non-clinical tests, it is the conclusion of Sedecal SA. that the modified PHOENIX Digital Diagnostic Mobile X-Ray 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.**