SEDECAL S.A.
% Daniel Kamm, P.E.
Principal Engineer
Kamm & Associates
8870 Ravello Ct
NAPLES FL 34114

January 26, 2018

Re: K173299
Trade/Device Name: DRAGON X SPSL4HC; DRAGON X SPSL8HC
Regulation Number: 21 CFR 892.1720
Regulation Name: Mobile x-ray system
Regulatory Class: II
Product Code: IZL, MQB
Dated: October 9, 2017
Received: October 17, 2017

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.

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.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Michael D. O'Hara 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)*
K173299

Device Name
DRAGON X SPSL4HC; DRAGON X SPSL8HC

Indications for Use *(Describe)*
These Portable Diagnostic 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. (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 K173299

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: October 9, 2017

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

1. **Identification of the Device:**
   Trade/Device Names: DRAGON X SPSL4HC; DRAGON X SPSL8HC
   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:** K121410
   Trade/Device Name: Sedecal Digital Portable X-ray Units: SPSLW4 and SPSLW8 ("Dragon LW")
   Manufacturer: Sedecal SA
   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)** These Portable Diagnostic 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. (Not for mammography).

4. **Description of the Device**: DRAGON X SPSL4HC and DRAGON X SPSL8HC are mobile x-ray units that cover all the specific needs of any radiographic examination at the patient's bed, first aid, and emergency, orthopedics, pediatric, and operating theater. These line operated units combine stand-alone feature for exposures for ease in imaging. Two different models of digital image acquisition panels are offered: FDX3543RP and FDX3543RPW. Both of the Toshiba panels and the associated software have been previously cleared by FDA (K130883). Integration with the portable 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: Manufacturer of the digital panel and the accompanying software.
   We have updated the User Manuals to reflect the changes made to the device.

5. **Safety and Effectiveness, comparison to predicate device.** Bench, test laboratory results, and risk management evaluations 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 Digital Portable X-ray Units: SPSLW4 and SPSLW8 ("Dragon LW") K121410**	**SEDECAL DRAGON X SPSL4HC; DRAGON X SPSL8HC K173299**
Intended Use:	These Portable Diagnostic 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. (Not for mammography).	SAME
Configuration	Line operated portable	SAME
Performance Standard	21 CFR 1020.30	SAME
Generator	High frequency made by Sedecal	SAME
Generator power level	Two available power levels: 4 KW, 8 KW	SAME
Collimator	Ralco R72S (K030487)	SAME
Image acquisition	Canon CXDI-501, CXDI-70C, or CXDI-80C.	Toshiba FDX3543RP and FDX3543RPW as cleared in K130883
Digital Panel Specifications	CXDI-501: 125 µ, 2800 x 3408 pixels CXDI-70C: 125 µ, 2800 x 3408 pixels CXDI-80C: 125 µ, 2192 x 2800 pixels	FDX3543RP: 143 µ 2448 ×2984 pixels FDX3543RPW: 140 µ, 2466 ×3040 pixels cleared in K130883
Software	Canon	eCom software as cleared in K130883
Connection	Ethernet or Wi-Fi	SAME
DICOM	YES	YES
Power Source	AC Line	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

Characteristic	Sedecal Digital Portable X-ray Units: SPSLW4 and SPSLW8 ("Dragon LW") K121410	SEDECAL DRAGON X SPSL4HC; DRAGON X SPSL8HC K173299
Standards (Other than Electrical and EMC)	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.	SAME
Photos		

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. A 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, generator testing, including generator controls (voltage, current, timing), and image acquisition.

8. Summary of Clinical Testing: Not required because the proposed digital panels have prior FDA clearance.

9. Conclusion After analyzing bench and laboratory testing to applicable standards, it is the conclusion of Sedecal SA that the modified Sedecal Portable 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.