November 3, 2021

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

Re: K212515
Trade/Device Name: MOVIX DReamy
Regulation Number: 21 CFR 892.1720
Regulation Name: Mobile X-Ray System
Regulatory Class: Class II
Product Code: IZL, MQB
Dated: August 5, 2021
Received: August 10, 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)*
K212515

Device Name
MOVIX DReamy

Indications for Use *(Describe)*
This Digital Mobile Diagnostic X-Ray System 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. 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 K212515

Stephanix
10 Rue Jean Moulin
La Ricamarie Auvergne-Rhone-Alpes, FR 42150
(Tel): +33 4 77 47 81 60
Registration Number: 3006972752
Date Prepared: October 22, 2021
Contact: Sandie Perret Quality Manager

1) **Identification of the Device:**
Trade/Device Name: MOVIX DReamy
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 (K131106, K133693, K170332 and K171270 with software update cleared in K190368) without modification:
Trade/Device Name: Canon Digital X-ray Panels
CANON CXDI-401C Wireless
CANON CXDI-701C Wireless
CANON CXDI-801C Wireless
CANON CXDI-710C Wireless
CANON CXDI-810C Wireless
CANON CXDI-410C Wireless
Regulation Number: 21 CFR 892. 1680
Regulation Name: Stationary x-ray system
Regulatory Class: II
Product Code: MQB

4) **Indications for Use:** This Digital Mobile Diagnostic X-Ray System 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.

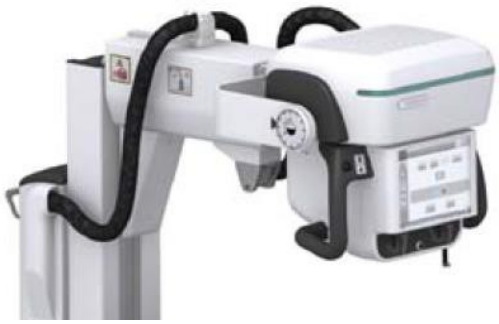
Applications can be performed with the patient sitting, standing, or lying in the prone or supine position. Not for mammography.

5) **Description of the Device**: These are modified versions of the predicate mobile digital diagnostic x-ray systems. They feature motorized movement and full battery operation. Various Canon digital X-ray panels are supplied with the system. (See list above.) The Mobile X-Ray Unit MOVIX DReamy has a Basic configuration or Advanced configuration. Advanced configurations include:
- Second screen on head assembly.
- Smooth movements of head assembly.
- Telescopic arm in four steps instead three steps for basic configuration.

The Mobile X-Ray unit MOVIX DReamy is provided with touch screen to operate as a control console. The Digital Imaging System is composed by image receptors and application for image acquisition (control console & image processing controller). The Image acquisition software "CANON CXDI Control Software NE" runs on MOVIX DReamy and it is displayed on touch screen. It is the user interface and compatible digital detectors are listed above. All have FDA Clearance. The Advanced configuration has a second Touch Screen Monitor located on head-assembly.

The MOVIX DReamy Mobile X-Ray Unit is provided with separate battery packs for X-Ray generation and motorized movements of the unit. The unit can operate connected to mains or in stand-alone mode, that is, operating without mains being present or unplugged from mains. The unit is connected to mains to charge the batteries; Rating: the input voltage range goes from 100 V~ to 240 V~, 1 phase, 1.1 kVA. New X-ray generator (model SHFM) is mounted on Battery Mobile X-Ray unit MOVIX DReamy This X-Ray generator for MOVIX DReamy Mobile X-Ray Unit has a radiogenic unit mounted on head-assembly and comprising an X-ray tube with rotating anode and its circuit for high voltage. The electronic and associated software to control the X-ray generation are placed on mobile cart. The Battery Mobile X-Ray Unit MOVIX DReamy is provided with different output powers: 20 kW, 32 kW, 40 kW and 50 kW. There are available two X-ray tube inserts with rotating anode manufactured by CANON ELECTRON TUBES & DEVICES:
- XRR-3331 insert.
- E7886 insert.

The Manual Beam Limiting Device is from Ralco, model: R108 F. External interface (controls) and covers are provided by Sedecal. There are two versions of collimator assembly, Basic and Advanced.

Basic	Advanced
	

Basic	Advanced
Knobs to adjust the collimator blades. Collimator light push button. Rail system to install external additional filtration. Measuring tape to measure the SID. Double laser (optional) Motorized filter (optional)	Knobs to adjust the collimator blades. Collimator light push button. Rail system to install external additional filtration. Measuring tape to measure the SID. Double laser (optional) Motorized filter (optional) Rear knobs to adjust the collimator blades (optional). Additional options selectable with TFT: Variable additional filtration. Collimator blades aperture.

The Battery Mobile X-Ray Unit MOVIX DReamy is driven by holding the handlebar with the hands. It is provided to internal sensor (gauges) that control the direction and speed of each wheel depending the force applied by the operator.
The handlebar is capacitive handlebar and when operator put his hands-on handlebar the movements are enabled. The height of handlebar is adaptable to improve the user commodity.

Four buttons are provided on the hand grips placed on Head-Assembly. They control the motion of each driving wheel and allow fine positioning adjustment of the unit respect the patient (movements with low speed because this control is not intended for long displacement).
The Battery Mobile X-Ray unit MOVIX DReamy supports:

- Ethernet communication (with hospital and backup cable for digital detectors)
- Wireless Wi-Fi communications (with digital detectors and remote hand switch). The wireless communication is supported by Access Point and one single internal antenna.

Options:
Barcode scanner for register patient information.
Dosimetry for Dose Area Product (DAP).

Tube Arm specifications:
- Counterbalanced tube arm.
- Tube arm reach 1220 mm horizontally for both configurations (Advanced option with 4 steps and Basic option with 3 steps).
- Column rotation: ± 317 °.
- Maximum SID to floor is 2020 mm for both configurations.
- Minimum SID to floor is 530 mm for both configurations.

Mobile Unit:
- Weight: the heaviest configuration 520 kg.
- Size (L x W x H):
  - o Mobile on parking position: 1220 x 540 x 1290 mm.
  - o Mobile fully extended (Telescopic column & Telescopic arm): 2290 x 1790 x 2230 mm.
- Frontal anti-collision system.
- Motorized unit up to 5,5 km/h.
- Motor drive with two independent drive motors, one for each wheel (forward and reverse).
- Touch screen console:
  - o Main control console: 19 inch.
  - o Additionally, second touch screen of 8.4 inch for Advanced configuration

6) Substantial Equivalence Chart

Characteristic	PhoeniX K192011 (Sedecal)	MOVIX DReamy
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 Digital Mobile Diagnostic X-Ray System 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. Not for mammography. (SAME, device description added)
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	SAME
Photos		
Digital X-ray Panel Supplied	CANON CXDI-401C Wireless CANON CXDI-701C Wireless CANON CXDI-801C Wireless Plus: CANON CXDI-710C Wireless CANON CXDI-810C Wireless CANON CXDI-410C Wireless	SAME

Characteristic	PhoeniX K192011 (Sedecal)	MOVIX DReamy
Software	Canon control software CXDI-NE	SAME
Panel Interface	Ethernet or Wi-Fi wireless	SAME
Meets US Performance Standard	YES 21 CFR 1020.30	SAME
Power Source	Universal power supply, from 100 V~ to 240 V~. 1 phase, 1.1 kVA	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.

8) **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*. The digital panel software employed was already reviewed by FDA in K190368. Because the units are indicated for the pediatric population (as well as the adult population) we reviewed and took into account the FDA guidance *Pediatric Information for X-ray Imaging Device Premarket Notifications.*
The MOVIX DReamy 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 2.0)**
   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 clinical tests, it is the conclusion of STEPHANIX that the new MOVIX DReamy 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.**