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

Meridian Medical Systems, LLC
% Daniel Kamm, P.E.
Submission Correspondent
Kamm & Associates
8870 Ravello Ct
NAPLES FL 34114

October 21, 2016

Re: K162687
Trade/Device Name: Paragon 2
Regulation Number: 21 CFR 892.1720
Regulation Name: Mobile x-ray system
Regulatory Class: II
Product Code: IZL, MQB
Dated: September 24, 2016
Received: September 27, 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,

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)*
K162687

Device Name
Paragon 2

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.

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510(k) Summary 510(k) Number K162687

MERIDIAN MEDICAL SYSTEMS LLC
352 Harris Drive
Aurora , OH 44202
Date Prepared: October 17, 2016
Contact: Larry Cornell, <lcornell@meridianmed.net>

1. **Identification of the Device:**
   Trade/Device Name: Paragon 2
   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:** K161345
   Trade/Device Name: RadPRO® Mobile 40kW; RadPRO® Mobile 40kW FLEXPLUS, Model SM-40HF-B-D-VIR.
   Manufacturer: Sedecal SA (Spain)
   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. **Reference device:** K143232 (The mobile device incorporates this device)
   Trade/Device Name: Universal Digital Interface 2W, UDI 2W.
   Manufacturer: MERIDIAN MEDICAL SYSTEMS LLC
   Regulation Number: 21CFR892.1680
   Regulation Name: Stationary X-ray System
   Regulatory Class: II
   Product Code: MQB
   Common/Usual Name: Digital X-ray panel and software

4. **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.

5. **Description of the Device**: The Paragon 2 is a mobile x-ray unit 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. Any of the following digital x-ray acquisition panels are available: Toshiba's FDX4343RPW, FDX 3543RPW, or FDX2520RPW. Integration of the panels and the software with the mobile system was straightforward since the panels and software have already been cleared. (K130883) The device complies with the US Federal Safety Performance Standard and is UL listed. The Paragon 2 has a telescoping tubestand which enhances visibility while transporting the unit. The Paragon 2 employs the digital x-ray panels and software employed in our premarket notification K143232.

6. **Safety and Effectiveness, comparison to predicate device.** Bench, test laboratory results, risk analysis and software validation and integration testing results 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**.**

7. Substantial Equivalence Chart

Characteristic	**K161345 Trade/Device Name: RadPRO® Mobile 40kW; RadPRO® Mobile 40kW FLEXPLUS,**	**Meridian Medical Paragon 2**
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	SAME
Configuration	Battery or line operated mobile	SAME
Performance Standard	21 CFR 1020.30	SAME
Generator	High frequency made by Sedecal	SAME
Generator power level	One available power level: 40 kW	Four available power levels: 20 KW, 32 KW, 40 KW, 50 KW. These four power levels were cleared in Sedecal's K101517 which was the predicate for K161345. Those same generators are used in the Paragon 2.
Collimator	Ralco R221 DHHS Manual Collimator	SAME

Characteristic	K161345 Trade/Device Name: RadPRO® Mobile 40kW; RadPRO® Mobile 40kW FLEXPLUS,	Meridian Medical Paragon 2
Image acquisition	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 Canon CXDI 701G Wireless (GOS) K131106 Pixel size: 125 µm 2800 × 3408 pixels Canon CXDI 801C Wireless (CSI) K131106 Pixel size: 125 µm 2800 × 2192 pixels Canon CXDI 801G Wireless (GOS) K131106 Pixel size: 125 µm 2800 × 2192 pixels	Toshiba panels are employed: FDX4343R/RPW, Active Area 43 (H)×43 (V) cm Pixel Matrix 3036 (H)×3040 (V) Pixel Pitch 140µ m FDX3543RP/RPW Active Area 345(H)×423(V)mm Pixel Matrix 2466(H)×3040(V) Pixel Pitch 140µ m FDX2530RPW. Active Area 245 (H)×295 (V) mm Pixel Matrix 1750 (H)×2108 (V) Pixel Pitch 140µ m The Paragon 2 employs the digital x-ray panels and software employed in our premarket notification K143232.
Software	Canon control software CXDI-NE	ECOM DROC, cleared with Toshiba panels (Sedecal) in K130883 AND K143232.
Connection	Ethernet or Wireless Wi-Fi	SAME
DICOM	YES	YES
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

Characteristic	K161345 Trade/Device Name: RadPRO® Mobile 40kW; RadPRO® Mobile 40kW FLEXPLUS,	Meridian Medical Paragon 2
Photo	RadPRO® Mobile  RadPRO® Mobile Flex Plus 	Standard Column  Telescopic Column 

8. 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. Software integration testing and risk analysis was performed to confirm proper implementation of the (already cleared) software. 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.

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

10. Conclusion After analyzing bench and laboratory testing to applicable standards, it is the conclusion of Meridian Medical that the Paragon 2 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.