DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

December 12, 2016

Source-Ray, Inc.
% Daniel Kamm, P.E.
President
Kamm & Associates
8870 Ravello Court
NAPLES FL 34114

Re: K163063
Trade/Device Name: UC-5000 Mobile X-ray
Regulation Number: 21 CFR 892.1720
Regulation Name: Mobile x-ray system
Regulatory Class: II
Product Code: IZL, MQB
Dated: September 24, 2016
Received: November 2, 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,

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)*
K163063

Device Name
UC-5000 Mobile X-Ray

Indications for Use *(Describe)*
The UC-5000 Mobile X-Ray is intended for General Purpose Radiographic exams utilizing film, computed radiography, or direct digital flat panels. 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 K163063

Source-Ray, Inc.
50 Fleetwood Court
Ronkonkoma, NY 11779
(631) 244-8200
Date Prepared: December 2, 2016
Contact: Ray Manez, President

1. **Identification of the Device:**
   Proprietary-Trade Name: UC-5000 Mobile X-Ray
   Classification Name: Mobile x-ray system
   Regulation Number: 21CFR §892. 1720,
   Regulation Name: Mobile x-ray system
   Regulatory Class: II
   Product Codes: IZL and MQB

2. **Equivalent legally marketed device: K090655, Trade/Device Name: PowerMax 1260 Portable X-Ray System, manufactured by Source-ray, Inc.**
   Regulation Number: 21CFR §892. 1720,
   Regulation Name: Mobile x-ray system,
   Regulatory Class: II
   Product Code: IZL

3. **Indications for Use (intended use): The UC-5000 Mobile X-Ray is intended for General Purpose Radiographic exams utilizing film, computed radiography, or direct digital flat panels. Not for mammography.**

4. **Description of the Device: The UC-5000 Mobile X-Ray consists of an X-ray generator, continuously adjustable light beam collimator, mounting arm, exposure cord with exposure switch, and AC power cord. This is a high-frequency generator of updated design.**
   Light Weight (no batteries)
   No Special Power Requirements (115/220 VAC Power Input)
   High Frequency 5.0 kW Generator with Closed loop regulation
   Digital Displays: kVp, mA, mAs & exposure time.
   Optionally available with the system is an FDA cleared digital panel and software combination.

5. **Safety and Effectiveness, comparison to predicate device. The results of bench testing, safety agency testing, risk analysis, and software validation indicates that the new device is as safe and effective as the predicate device. Proper system operation is fully verified upon installation.**

6. Substantial Equivalence Chart

	K090655 Model PowerMax 1260 Portable X-Ray System	**UC-5000 Mobile X-Ray**
Intended Use:	The Model PowerMax 1260 Portable X-Ray System is intended for General Purpose Portable Radiographic Applications **(Not for mammographic use. Language later required by FDA)**	The UC-5000 Mobile X-Ray is intended for General Purpose Radiographic exams utilizing film, computed radiography, or direct digital flat panels. Not for mammographic use. (Language added for CR/DR)
Size / weight:	110 lbs. / 50 kG	340 lb., 154.2 KG
Energy Source:	120/220 V 50 – 60 Hz AC	SAME
Use Interface:	Dedicated Touch Panel	SAME
Exposure times:	0.01 – 3.33 sec	.01 – 5.00 sec
mA Range	12.5-60	10 - 50 mA
Control	Microprocessor	SAME
HF Generator	30 kHz	SAME
kW	3 kW	5.0 kW
kVp:	40 – 120kVp 80 steps	40 – 110kVp 41 steps
X-ray Tube	SXR-130-15-1.2; Stationary Anode 130 kVp Target Material Tungsten Anode Capacity 45,000 HU Storage Focal Spot 1.2 mm; Target Angle 15°	SAME
CR/DR Compatible	YES	SAME, now available with OPTIONAL computer, panel, and software **Flat Panel:** ViZion DR Panel 14 x 17 Wireless, Viztek (K152279), High Quality Wireless 14" X 17" Digital Panel, Amorphous Silicon Scintillator 150 x 150 micron pixel size **Software**: Opal Rad Imaging Software Viztek also cleared in K152279. Features: Window / Level; Image Preview; DICOM Print / Store; Fast Image Processing; (image displayed within 3 seconds); **Computer**: 20" All-In-One Tabletkiosk PC (TAIO20T) with Touch

	K090655 Model PowerMax 1260 Portable X-Ray System	UC-5000 Mobile X-Ray
		Screen
Collimator	Collimare Model CPL-125-UC01-C	SAME
Standards	This device complies with all applicable performance standards under 21 CFR 1020.30 and 1020.31. IEC 60601-1: 2005 ANSI Medical electrical equipment - Part 1: General requirements for basic safety and essential performance IEC 60601-1-2: 2014 Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and test	This device complies with all applicable performance standards under 21 CFR 1020.30 and 1020.31. SAME SAME
Photo		

	K090655 Model PowerMax 1260 Portable X-Ray System	UC-5000 Mobile X-Ray
Digital Panel	Not specified	ViZion DR Panel, 14 x 17 Wireless, Viztek (K152279) 

7. **Summary of non-clinical testing: Software validation and risk analysis was performed. NRTL Laboratory testing was performed according to the following standards: IEC 60601-1 and IEC 60601-1-2. This device complies with all applicable performance standards under 21 CFR 1020.30 and 1020.31. Performance testing over the range of possible AC line voltages checked: kVp calibration at high and low ma; ma calibration at high and low ma; timer tests; mAs display; Half Value Layer; reproducibility; linearity; radiation leakage; collimator light illuminance and alignment; and x-ray field coverage. The optional digital imaging components were assembled, tested, and calibrated per the originally FDA cleared instructions provided by the original equipment manufacturers. Test images showed the generator + panel system performs as intended. A calibration procedure was written for the end user and was executed properly in our factory.**

8. **Summary of clinical testing: Not applicable. Clinical testing was not deemed to be required to show substantial equivalence. We relied on non-clinical testing and compliance with standards.**

9. **Conclusion: After analyzing software validation, bench tests, test images, and safety agency test reports, it is the conclusion of Source-ray, Inc. that the UC-5000 Mobile X-Ray 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.**