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

Beijing Polycon Medical Engineering Company
% Daniel Kamm, P.E.
Principal Engineer
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8870 Ravello Court
NAPLES FL 34114

August 4, 2015

Re: K151219
Trade/Device Name: Models 2200DR and 1600DR Digital Stationary Radiographic Systems
Regulation Number: 21 CFR 892.1680
Regulation Name: Stationary x-ray system
Regulatory Class: II
Product Code: KPR, MQB
Dated: June 24, 2015
Received: June 30, 2015

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 A Ochs

Robert Ochs, Ph.D.
Acting 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)*
K151219

Device Name
Models 2200DR and 1600DR Digital Stationary Radiographic Systems

Indications for Use *(Describe)*
The Models 2200DR and 1600DR Digital Stationary 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)

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) K151219

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Date Prepared: June 13, 2015
Contact: Xiangchen Liu, President

1. **Identification of the Device:**
   Proprietary-Trade Name: Models 2200DR and 1600DR Digital Stationary Radiographic Systems
   Classification Name: Stationary X-Ray System, Product codes KPR and MQB
   Common/Usual Name: Digital Diagnositc X-Ray System
   Device Class: II per regulation 21CFR892.1680

2. **Equivalent legally marketed device: KrystalRad 1100 and KrystalRad 3000 Digital Stationary Radiographic Systems, K143257, MedicaTech USA.**
   Classification Name: Stationary X-Ray System, Product codes KPR and MQB
   Common/Usual Name: Digital Diagnositc X-Ray System
   Device Class: II per regulation 21CFR892.1680

3. **Indications for Use** The Models 2200DR and 1600DR 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: This device represents a new combination of an already cleared solid state digital x-ray acquisition panel and software with the diagnostic x-ray compnents required to make a complete system. The digital panel is the Toshiba wired flat panel detector FDX-4343R, 17 in x l7in. (Cleared in K143257 as well as other submissions.) The system has been tested with only this model of flat panel detector. The purchaser can select either a “C” arm configuration (1600DR) or an overhead tube crane configuration (2200DR). Please see the photos below. The x-ray generator is a CPI CMP 200DR. The x-ray tubes are supplied by Toshiba (E7252X Series), and the collimator is the Ralco R302A. The system complies with the CDRH Radiological Health performance standard in the Code of Federal Regulations, as well as the voluntary IEC standards IEC 60601-1, IEC 60601-1-2, and IEC60601-2-54. The systems include an AEC feature.

5. **Safety and Effectiveness, comparison to predicate device**. This combination device has the same indications for use and very similar technological characteristics as the predicate device, and employs already 510(k) cleared digital panels and software.

6. **Substantial Equivalence Chart: Please see the next page.**

Characteristic	KrystalRad 1100 and KrystalRad 3000 Digital Stationary Radiographic Systems, K143257, MedicaTech USA.	Models 2200DR and 1600DR Digital Stationary Radiographic Systems, Beijing Polycon Medical Engineering Company	Difference and Analysis
Intended Use:	KrystalRad Series 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.	Models 2200DR and 1600DR Digital Stationary 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)	NO DIFFERENCE
Configuration of Digital Panels	Battery or AC operated wireless IEEE 802.11n or Wired Ethernet	AC operated Wired Ethernet only.	Difference: There is no chance of wireless interference with the Polycon implementation.
Digital Panel Models and their clearance numbers	Vieworks/Medicatech FXRD-1717SA/SB, FXRD-1417SA/SB and FXRD-1417WA/WB (K130337) Toshiba: FDX4343R/RPW, FDX3543RP and FDX3543RPW (Del Medical: K140825; O&R: K131121; Sedecal: K130883); PerkinElmer: XRpad 4336 MED (K140551)	Toshiba: FDX4343R Cleared in the Predicate Device, K143257	NO DIFFERENCE
Image acquisition panel specifications	FXRD-1717SA/SB: 3,072 x 3,072, 140µm FXRD-1417SA/SB: 2560 x 3072, 140µm FXRD-1417WA/WB: 2560 x 3072, 140µm FDX4343R/RPW: 3008×3072, 143 µm FDX3543RP: 2448×2984, 143 µm FDX3543RPW: 2466×3040, 140µm XRpad 4336 MED: 3556×4320, 100 µm	FDX4343R 3008×3072, 143 µm	NO DIFFERENCE

Characteristic	KrystalRad 1100 and KrystalRad 3000 Digital Stationary Radiographic Systems, K143257, MedicaTech USA.	Models 2200DR and 1600DR Digital Stationary Radiographic Systems, Beijing Polycon Medical Engineering Company	Difference and Analysis
AEC	YES	YES	NO DIFFERENCE
DICOM	DICOM 3	DICOM 3	NO DIFFERENCE
Image acquisition software	CrystalRad as cleared in K130377	ECOM Software	DIFFERENT SOFTWARE: Software was as cleared in: K130883. That submission used the same Toshiba panel, FDX4343R We verified proper operation of the ECOM software via Clinical Testing.
Power Source	AC Line, various voltages available	SAME	NO DIFFERENCE
Photo	Krystalrad 3000 	2200DR 	NO DIFFERENCE
Alternate configuration	KrystalRad 1100 	1600DR 	NO DIFFERENCE
Generator	CPI CMP 200DR	CPI CMP 200DR	NO DIFFERENCE
Collimator	Ralco R302A	Ralco R302A	NO DIFFERENCE
Tube Head	Toshiba	Toshiba	NO DIFFERENCE
Performance Standard	FDA 21CFR1020.30-31	SAME	NO DIFFERENCE
Electrical safety	Electrical Safety per IEC-60601. UL listed	SAME	NO DIFFERENCE

7. **Summary of non-clinical testing**: We performed integration testing and risk analysis. The results of a review of bench, safety test, and software validation documentation indicates that the new device is as safe and effective as the predicate device. The device conforms to US Performance Standards. The device conforms to this list of voluntary standards:

Standards No.	Standards Organization	Standards Title	Version	Date
60601-1	IEC	Safety of Electrical Medical Equipment	2005 + A1 (2012)	2005 + A1 (2012)
60601-1-2	IEC	Electromagnetic Compatibility	2007	2007
60601-2-54	IEC	Particular requirements for the basic safety and essential performance of X-ray equipment for radiography and radioscopy	2009 1ed	2009
PS 3.1 - 3.18 (2009	NEMA	Digital Imaging and Communications in Medicine (DICOM) Set (This applies to the Digital Panel)	3	2009

8. **Summary of clinical testing**: Clinical images were provided; these images were not necessary to establish substantial equivalence based on the modifications to the device (e.g., use of previously cleared detectors) but they provide further evidence in addition to the laboratory performance data to show that the complete system works as intended.

9. **Conclusion:** After analyzing software integration validation, safety testing data, and clinical images, it is the conclusion of Beijing Polycon that the "Models 2200DR and 1600DR Digital Stationary Radiographic Systems" are as safe and effective as the predicate device, have few technological differences, and has identical indications for use, thus rendering it substantially equivalent to the predicate device.