DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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February 24, 2017

Arquilla, Inc. DBA X-Cel X-Ray Corporation
% Cynthia J. Pillar, RAC
Regulatory Consultant
CJP Consulting, Inc.
5831 N. Kostner Avenue
CHICAGO IL 60646

Re: K160857
Trade/Device Name: HF 718BD X-Ray System
Regulation Number: 21 CFR 892.1680
Regulation Name: Stationary x-ray system
Regulatory Class: II
Product Code: KPR
Dated: November 29, 2016
Received: February 13, 2017

Dear Ms. Pillar:

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)*
K160857

Device Name
HF 718BD X-Ray System

Indications for Use *(Describe)*
The HF 718BD X-Ray System is intended for use by qualified clinicians for the x-ray of hands and feet.

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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SECTION 5: 510(k) SUMMARY

510(k) Summary – TRADITIONAL 510(k)

Date Prepared:	November 28, 2016
Submitter:	X-Cel X-Ray Corporation 4220 Waller Street Crystal Lake, IL 60012 Phone: 1 (815) 455-2470 Facsimile: 1 (815) 455-4732
Contact:	Cynthia J. Pillar, Regulatory Consultant 1 (773) 677-8886
Trade/Proprietary Name of Device:	Model HF 718BD X-Ray System
Common Name of Device:	Stationary x-ray system
Classification:	Class II per 21 CFR 892.1680, System, X-Ray, Stationary, Product Code KPR
Legally Marketed Predicate Device:	X-Cel X-Ray Model 700 Series P-75W/P-75M, manufactured by X-Cel X-Ray Corporation (K811230)

5.1 Description of the New MODEL HF 718BD X-RAY SYSTEM

The new MODEL HF 718BD X-RAY SYSTEM is a stationary x-ray system for imaging of peripheral extremities. The new MODEL HF 718BD X-RAY SYSTEM is based on the predicate Model 715BD Series X-Ray System. The modifications to the Model 715BD Series X-Ray System to create the new MODEL HF 718BD X-RAY SYSTEM are summarized as:

1. The analog high voltage power supply in the predicate Model 715BD Series is replaced by a high-frequency high-voltage power supply in the new MODEL HF 718BD X-RAY SYSTEM.

2. The line frequency counting technology of the exposure timer in the predicate Model 715BD Series is replaced by a crystal controlled digital exposure timing system in the new MODEL HF 718BD X-RAY SYSTEM.
3. The current technique factors are moderately decreased from fixed 15 mA to fixed 10 mA in the new MODEL HF 718BD X-RAY SYSTEM.
4. The voltage display on the predicate Model 715BD is an analog meter. With the new MODEL HF 718BD X-RAY SYSTEM, the user sets the kV and exposure time (can be stored as a user preset) and the pre-set values are presented to the user on a digital display.

The Source to Detector distance for the new MODEL HF 718BD X-RAY SYSTEM is 29 inches, which is identical to the predicate Model 715BD. In addition to the exposure control microcontroller in the predicate Model 715BD Series, an additional microcontroller is applied in the power supply to receive communication of kV by the x-ray control unit in the new MODEL HF 718BD X-RAY SYSTEM.

5.2 Intended Use of the Device

The intended use of the new MODEL HF 718BD X-RAY SYSTEM is identical to the predicate device. Both devices are stationary X-ray systems intended for use in clinical settings by qualified clinical professionals for X-ray of peripheral extremities such as the hand and foot.

5.3 Indication for Use Statements

The Indications for Use of the new MODEL HF 718BD X-RAY SYSTEM is equivalent to the predicate device:

The Model HF 718BD X-Ray System is intended for use by qualified clinicians for the x-ray of hands and feet.

5.3 Summary of Technological Characteristics

The following table provides a side-by-side comparison the new MODEL HF 718BD X-RAY SYSTEM to the predicate device applied to support this notification.

Table 5.3-1: Substantial Equivalence Technical Characteristics

Feature or Component	NEW Model HF 718BD X-Ray System	Predicate Model 700 Series P-75W/P-75M (K811230)	Variance Explanation:
Indications for Use	The Model HF 718BD X-Ray System is intended for use by qualified clinicians for the x-ray of hands and feet.	The HF718 X-Ray System is intended for general purpose peripheral radiographic applications.	Equivalent – added specification for use by clinicians and specified 'peripheral' as hands and feet.
Tube	Same	Same	Identical
Tube Housing Assembly	Same	Same	Identical
Controller	Firmware exposure control.	Firmware exposure control.	Identical
Display	Touch Screen	Analog knob & numeric keypad	Similar, increased flexibility for user selection of settings.
Exposure Timer	Firmware with crystal timing	Firmware with AC line timing	Similar, both methods set the exposure time.
Orthoposer, (Film Holder, Image Detector)	Same	Same	Identical
High voltage Power Supply	High frequency generator	Half wave rectified	Similar, tested successfully to IEC 60601-1.
Beam Limiting Device	Same	Same	Identical
High Voltage Setting	Pre-set and by user entry 50kV to 90kV +/- 10% adjustable in 2 kV steps	Pre-set by rotary control 50kV to 70kV+/- 10%	Similar, both devices support preset of the kVp and time technique factors.

mA Setting	Fixed at 10mA +/-1%	Fixed at 15mA	Similar, both devices support preset of the kVp and time technique factors.
Technique Factors Display	Digital display of user-set Voltage and Exposure Time technique factors	Analog display of Voltage and mA technique factors. Digital display of exposure time	Similar, analog display of Voltage and mA replaced by digital display.
Exposure Timer Settings	Pre-set and user-defined exposure time settings	User-defined exposure timer	Similar – additional feature of pre-sets.
Exposure Timer Display	Digital display of seconds of exposure	Digital display of count of 60Hz line frequency of exposure	Similar – modified display to show seconds of exposure.
Power	60Hz AC mains; 105 VAC to 130 VAC	60Hz AC mains; 105 VAC to 130 VAC	Identical
Exposure Time	0.050 to 0.500 seconds, +/-10%, adjustable in steps	0.10 to 3.0 seconds,+/-10%, adjustable in steps	Similar, High frequency generator allows for shorter exposure time.
Source to Detector Distance	29 inches	29 inches	Identical

TABLE 5.3-1 – SUBSTANTIAL EQUIVALENCE TECHNICAL CHARACTERISTICS

The new MODEL HF 718BD X-RAY SYSTEM has been tested for performance. The technological differences between the new MODEL HF 718BD X-RAY SYSTEM and the predicate have raise no new question with regard to safety or effectiveness.

5.4 Determination of Substantial Equivalence – Clinical

This submission does not contain clinical data.

5.4 Determination of Substantial Equivalence - Non-clinical

The new MODEL HF 718BD X-RAY SYSTEM was subjected to testing to applicable regulations and standards to support the claim of substantial equivalence as shown in Table 5.4-1 below:

Table 5.4-1: Regulation and Standards	
Test/Performance Standard Reference:	**Test/Standard Title:**
21 CFR 1020.30	Diagnostic x-ray systems and their major components.
21 CFR 1020.31	Radiographic equipment
60601-1 3rd Edition	Medical electrical equipment - Part 1: General requirements for safety
60601-1-2 3rd Edition	Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance – Collateral Standard: Electromagnetic compatibility – Requirements and tests
60601-1-6	Medical electrical equipment – Part 1-6: General requirements for basic safety and essential performance – Collateral Standard: Usability
62304:2006	Medical device software – Software life cycle processes
60601-2-54:2009 – Ed.1.0	Medical electrical equipment – Part 2-54: Particular requirements for the basic safety and essential performance of X-ray equipment for radiography and radioscopy
60601-3:2008-Ed. 2.0	Medical electrical equipment – Part 1-3: General requirements for basic safety and essential performance – Collateral Standard: Radiation protection in diagnostic X-ray equipment
IEC TR 60878	Graphical symbols for electrical equipment in medical practice
EN ISO 14971	Application of risk management to medical devices
ISO 15223-1	Medical devices – Symbols to be used with medical device labels, labeling, and information to be supplied

TABLE 5.4-1 – REGULATIONS AND STANDARDS

The new MODEL HF 718BD X-RAY SYSTEM was designed by X-Cel X-Ray Corporation in compliance with 21 CFR 820. The new MODEL HF 718BD X-RAY SYSTEM has undergone software validation as well as performance verification and validation to ensure it meets all design inputs and performance requirements.

5.5 Conclusion

The conclusions drawn from the specifications and performance testing of the new MODEL HF 718BD X-RAY SYSTEM demonstrate that the new MODEL HF 718BD X-RAY SYSTEM is at least as safe and effective and performs as well or better than the predicate X-Cel X-Ray Model 700 Series P-75W/P-75M, manufactured by X-Cel X-Ray Corporation (K811230). For these reasons, we believe the new MODEL HF 718BD X-RAY SYSTEM device is substantially equivalent to the predicate device.