November 1, 2022

Suzhou Powersite Electric Co., Ltd.
℅ Xinyue Lu
Regulatory Engineer
Building 5, No.188 Fuchunjiang Road, Suzhou New District
Suzhou, Jiangsu Province 215151
CHINA

Re: K222258
Trade/Device Name: Combined High Frequency X-ray Source
Regulation Number: 21 CFR 892.1720
Regulation Name: Mobile x-ray system
Regulatory Class: Class II
Product Code: IZL
Dated: July 18, 2022
Received: September 6, 2022

Dear Xinyue Lu:

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

Laurel Burk, Ph.D.
Assistant Director
Diagnostic X-Ray Systems Team
DHT8B: Division of Radiological Imaging Devices and Electronic Products
OHT8: Office of 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)*
K222258

Device Name
Combined High Frequency X-ray Source

Indications for Use *(Describe)*
The Combined High Frequency X-ray Source is intended for use by a qualified/trained technician on both adult and pediatric subjects for body extremities and cervical spine exclusively. 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) Submission Number: K222258

I. SUBMITTER

Suzhou Powersite Electric Co., Ltd
Building 5, No.188 Fuchunjiang Road, Suzhou New District,
Suzhou, Jiangsu Province, PEOPLE'S REPUBLIC OF CHINA

Phone: +86-0512-62913368

Contact Person: Yanyan Cui
Phone: +86-13771842733
E-mail: may_cui@powersite-group.com

Primary correspondent
Name: Xinyue Lu
Title: Regulatory Engineer
Phone: +86-13722611742
E-mail: xinyue_lu@powersite-group.com

Date Prepared: June 15, 2022

II. DEVICE

Name of Device: Combined High Frequency X-ray Source
Model: PSM-PD5.6CPL, PSM-PD5.6CPLG, PSM-PD4CPL, PSM-PD4CPLG, PSM-PD3.5CPL, PSM-PD3.5CPLG, PSM-PD5.6CPE, PSM-PD5.6CPEG, PSM-PD4CPE, PSM-PD4CPEG, PSM-PD3.5CPE, PSM-PD3.5CPEG
Common or Usual Name: Combined High Frequency X-ray Source
Classification Name: System, X-Ray, Mobile (21 CFR 892.1720)
Regulatory Class: II
Product Code: IZL
Regulation Medical Specialty: Radiology

III. PREDICATE DEVICE

Device Classification Name: system, x-ray, mobile
510(k) Number: K103522
Device Name: SEDECAL
Proprietary-Trade Name: Sedecal SPL-HF-4.0 (and SPL-HF-2.0)
Common/Usual Name: Mobile Diagnostic X-Ray System
Applicant: SEDECAL S.A.
8870 RAVELLO
NAPLES, FL 34114
Regulation Name and Number: 21 CFR 892.1720
Device Class: 2
Classification Product Code: IZL
Regulation Medical Specialty: Radiology

This predicate has not been subject to a design-related recall.
No reference devices were used in this submission.

IV. DEVICE DESCRIPTION

PSM-PD series combined high frequency X-ray source is an advanced high frequency X-ray source, which is mainly composed of shell case, control panel mounting assembly, DCDC riser mounting assembly, power panel mounting assembly, ESU energy storage capacitor mounting assembly, high voltage TANK, collimator, Lithium battery. The product is small in size, light in weight and high in power density, which can meet the needs of outdoor portability. At the same time, we provide battery-powered solutions to meet customers' diversified demands for product functions.

The working flow of combined high-frequency X-ray source is as follows:
1) Input single-phase alternating current, through the filter circuit, reduce the influence of harmonics on mains power supply, APFC circuit will change AC into DC, improve the power factor of the product, through the filter circuit to reduce AC ripple.
2) The DC inverter is converted into high-frequency alternating current by the inverter, and the high-frequency low voltage is boosted into high-frequency high voltage by the boost transformer, and the AC is converted into high-voltage DC by the voltage multiplier, and finally the smooth high voltage is loaded at both ends of the ball tube through filtering.
3) Set different parameters and working modes through DSP+FPGA control unit.
4) Provide serial communication and wireless remote control functions.
5) Provide LCD operation and upper computer software control of two parameters, working mode setting.

Our company provides Combined High Frequency X-ray Source to the complete machine manufacturer. Then the complete machine manufacturers assemble the complete machine with our product and sell the complete machine to the hospital or others.

The associated consumables include:

- Mains power supply cord
- Hand switch control line
- Serial port transfer wiring
- Fuse(0215016.MXP)
- Fuse(8020.0604)
- Cross countersunk head screw(SUS304, M3*6)
- Cross flat head screw(SUS304, M3*8, head diameter 6mm)
- USB flash disk
- Automatic test report

V. INDICATIONS FOR USE

The Combined High Frequency X-ray Source is intended for use by a qualified/trained technician on both adult and pediatric subjects for body extremities and cervical spine exclusively. Applications can be performed with the patient sitting, standing, or lying in the prone or supine position. (Not for mammography)

The Indications for Use statement for the Powersite device is not identical to the predicate device; however, the differences do not alter the intended diagnostic use of the device nor do they affect the safety and effectiveness of the device relative to the predicate. Both the subject and predicate devices have the same intended use for X-ray photography of human limb joints and cervical spine in emergency rescue occasions, by cooperating with X-ray imaging device.

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

At a high level, the subject and predicate devices are based on the following same technological elements:

The working flow of combined high-frequency X-ray source is as follows:

1) Input single-phase alternating current, through the filter circuit, reduce the influence of harmonics on mains power supply, APFC circuit will change AC into DC, improve the power

factor of the product, through the filter circuit to reduce AC ripple.

2) The DC inverter is converted into high-frequency alternating current by the inverter, and the high-frequency low voltage is boosted into high-frequency high voltage by the boost transformer, and the AC is converted into high-voltage DC by the voltage multiplier, and finally the smooth high voltage is loaded at both ends of the ball tube through filtering.

3) Set different parameters and working modes through DSP+FPGA control unit.

4) Provide serial communication and wireless remote control functions.

5) Provide LCD operation and upper computer software control of two parameters, working mode setting.

The following technological differences exist between the subject and predicate devices:

Table 1 Comparison Table

Comparison item	The subject product	The predicate device(K103522)	Difference	Overview of supporting materials
Common/Usual Name of Device	Combined High Frequency X-ray Source	Mobile Diagnostic X-ray System	SE	User manual
Model Specification	PSM-PD5.6CPL、PSM-PD5.6CPLG、PSM-PD4CPL、PSM-PD4CPLG、PSM-PD3.5CPL、PSM-PD3.5CPLG、PSM-PD5.6CPE、PSM-PD5.6CPEG、PSM-PD4CPE、PSM-PD4CPEG、PSM-PD3.5CPE、PSM-PD3.5CPEG	Sedecal SPL-HF-4.0 (and SPL-HF-2.0)	SE	User manual
Indications for use	The Combined High Frequency X-ray Source is intended for use by a qualified/trained technician on both adult and pediatric subjects for body extremities and cervical spine exclusively. Applications can be performed with the patient sitting, standing, or lying in the prone or supine position. (Not for mammography)	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)	SE	User manual
Basic principle (Working	The working flow of combined high-frequency X-ray source is as follows:	The working flow of combined high-frequency X-ray source is as follows:	SE	User manual

principle / Action mechanism)	1. Input single-phase alternating current, through the filter circuit, reduce the influence of harmonics on mains power supply, APFC circuit will change AC into DC, improve the power factor of the product, through the filter circuit to reduce AC ripple. 2. The DC inverter is converted into high-frequency alternating current by the inverter, and the high-frequency low voltage is boosted into high-frequency high voltage by the boost transformer, and the AC is converted into high-voltage DC by the voltage multiplier, and finally the smooth high voltage is loaded at both ends of the ball tube through filtering. 3. Set different parameters and working modes through DSP+FPGA control unit. 4. Provide serial communication and wireless remote control functions. 5. Provide LCD operation and upper computer software control of two parameters, working mode setting.	1. Input single-phase alternating current, through the filter circuit, reduce the influence of harmonics on mains power supply, APFC circuit will change AC into DC, improve the power factor of the product, through the filter circuit to reduce AC ripple. 2. The DC inverter is converted into high-frequency alternating current by the inverter, and the high-frequency low voltage is boosted into high-frequency high voltage by the boost transformer, and the AC is converted into high-voltage DC by the voltage multiplier, and finally the smooth high voltage is loaded at both ends of the ball tube through filtering. 3. Set different parameters and working modes through DSP+FPGA control unit. 4. Provide serial communication and wireless remote control functions. 5. Provide LCD operation and upper computer software control of two parameters, working mode setting.		
Structural composition	Combined High Frequency X-ray Source	The predicate device consists of the	Difference: 1) The structure	User manual

	product consists of the control software (Release version: V1.0) and the host of Combined High Frequency X-ray Source. The host of Combined High Frequency X-ray Source is mainly composed of shell case, control panel mounting assembly, DCDC riser mounting assembly, power panel mounting assembly, ESU energy storage capacitor mounting assembly, high voltage TANK, collimator, Lithium battery.	control software and the host of Combined High Frequency X-ray Source. The host of the predicate device is composed of a control panel with a display, a power module, a high voltage tank (TANK), a collimator, a handswitch, and a mobile column with an articulated arm and a cassette basket.	composition is different. The predicate device is accompanied with a mobile column with articulated arm and cassette basket, which the subject device does not have.	
Basic parameter	1．AC power input 100V~240VAC, ±10% 50Hz/60Hz±1Hz 2．DC power input 48VDC/2A	1. AC power input 100~240VAC, ±10% VAC, 50/60Hz 2．DC power input 48VDC/2A		User manual

	3. Maximum nominal electrical power <table><tr><td>PSM-PD3.5CPL/CPLG PSM-PD3.5CPE/CPEG</td><td>3.2kW</td></tr><tr><td>PSM-PD4CPL/CPLG PSM-PD4CPE/CPEG</td><td>4.0kW</td></tr><tr><td>PSM-PD5.6 CPL/CPLG PSM-PD5.6CPE/CPEG</td><td>5.6kW</td></tr></table> 4. Maximum output electric power <table><tr><td>PSM-PD3.5CPL/CPLG PSM-PD3.5CPE/CPEG</td><td>3.6kW</td></tr><tr><td>PSM-PD4CPL/CPLG PSM-PD4CPE/CPEG</td><td>4.0kW</td></tr><tr><td>PSM-PD5.6 CPL/CPLG PSM-PD5.6CPE/CPEG</td><td>5.6kW</td></tr></table>	3. Maximum nominal electrical power SPL-HF4：4kW 4. Output power： SPL-HF4：4kW	Difference: 2) The maximum nominal electric power and the maximum output electric power are different. The maximum nominal electric power and the maximum output electric power in the model declared by the subject device are 5.6kW. While the maximum nominal electric power and the maximum output electric power in the model declared by the predicate device are 4kW.	

<table>
<tr>
<td>Normal operating condition</td>
<td>1. Temperature:
0~35℃(AC supply)
0~40℃(only for battery discharging)
2. Relative humidity:
95%, non-condensing;
3. Atmospheric pressure:
700hPa~1060hPa.</td>
<td>1. Temperature:
0~40℃
2. Relative humidity:
95%, non-condensing;
3. Atmospheric pressure:
700hPa~1060hPa.</td>
<td>SE</td>
<td>User manual</td>
</tr>
<tr>
<td>Performance requirements</td>
<td>1. X-ray tube voltage
a) Tube voltage regulation range:
40kV~125kV, 1kV step size, tube voltage can be set according to power.
<table>
<tr><th>Model</th><th>Tube voltage regulation range</th></tr>
<tr><td>PSM-PD5.6CPL/CPLG
PSM-PD5.6CPE/CPEG
PSM-PD4CPL/CPLG
PSM-PD4CPE/CPEG
PSM-PD3.5CPL/CPLG</td><td>40kV~125kV</td></tr>
</table>
</td>
<td>1. X-ray tube voltage
a) Tube voltage regulation range:
40~125kV, 1kV step size.
<table>
<tr><th>Model</th><th>Tube voltage regulation range</th></tr>
<tr><td>SPL-HF4</td><td>40~125kV</td></tr>
</table>
b) Tube voltage deviation: ±(3%+1kV)</td>
<td></td>
<td>User manual</td>
</tr>
</table>

	PSM-PD3.5CPE/CPEG | b) Tube voltage deviation: ±(3%+1kV) 2. X-ray tube current a) Tube current regulation range Model | Tube current regulation range PSM-PD3.5CPL/CPLG PSM-PD3.5CPE/CPEG | 5-63mA PSM-PD4CPL/CPLG PSM-PD4CPE/CPEG | 5-80mA PSM-PD5.6CPL/CPLG | 5-100mA	2. X-ray tube current a) Tube current regulation range Model | Tube current regulation range SPL-HF4 | 5~100mA 16 steps, the specific data are: 5, 6.4, 8, 10, 12.5, 16, 20, 25, 32, 40, 50, 64, 80, 100 mA b) Tube current deviation:	Difference: 3) The number systems of tube current, loading time and current time product are different. The subject device is distributed according to the R'20 number system, and the predicate device is distributed according to the R'10 number system and the user-defined number system.	

	PSM-PD5.6CPE	±(4% + 1 mA)		
	Increasing according to the number system R'20, the specific data are 5、5.6、6.3、7.1、 8、9、10、11、12.5、14、16、18、20、22、25、28、32、36、40、45、50、56、63、71、80、90、100。 b) Tube current deviation: ±(4% + 1 mA)			
	3. Loading time a) Loading time regulation range: 1ms～10000ms， Increasing according to the number system R'20, the specific data are 1、1.1、1.25、1.4、1.6、1.8、2、2.2、2.5、2.8、3.2、	3. Loading time a) Loading time regulation range: 1 ms~10000ms， Increase according to the number system R'10 (in 25% steps), for a total of 41 steps	Difference: 4) The loading time deviation is different. The loading time deviation of the subject device is larger than that of the predicate device. The	

	3.6、4、4.5、5、5.6、6.3、7.1、8、9、 10、11、12.5、14、16、18、20、22、 25、28、32、36、40、45、50、56、63、 71、80、90、100、110、125、140、 160、180、200、220、250、280、320、 360、400、450、500、630、710、800、 900、1000、1100、1250、1400、1600、 1800、2000、2200、2500、2800、3200、 3600、4000、4500、5000、6300、7100、 8000、900、10000； b) Loading time deviation: not greater than ±(2%+0.2ms) @ ＞5ms ±(5%+1ms) @ ≤5ms	b) Loading time deviation: ± (2% + 0.1ms)	deviation of the subject device is controlled within the scope of the international standard requirements.	

<table>
<tr>
<td></td>
<td>4. Current time product
a) Current time product regulation range:
<table>
<tr><th>Model</th><th>Current time product regulation range</th></tr>
<tr><td>PSM-PD3.5CPL/CPLG
PSM-PD3.5CPE/CPEG
PSM-PD4CPL/CPLG
PSM-PD4CPE/CPEG
PSM-PD5.6CPL/CPLG
PSM-PD5.6CPE/CPEG</td><td>0.1-320mAs</td></tr>
</table></td>
<td>4. Current time product
a) Current time product regulation range:
<table>
<tr><th>Model</th><th>Current time product regulation range</th></tr>
<tr><td>SPL-HF4</td><td>0.1 mAs ~ 250 mAs</td></tr>
</table>
Increase according to the number system R'10 (in 25% steps), a total of 34 steps

b) Current time product deviation:
± (5% + 0.1 mAs)</td>
<td>Difference:
5) The regulation range of current time product is different. The regulation range of current time product of the subject device is larger than that of the predicate device.</td>
<td></td>
</tr>
</table>

	Increasing according to the number system R'20, the specific data are 0.1、0.11、0.12、0.14、0.16、0.18、0.2、0.22、0.25、0.28、0.32、0.4、0.45、0.5、0.56、0.63、0.71、0.8、0.9、1、1.1、1.25、1.4、1.6、1.8、2、2.2、2.5、2.8、3.2、3.6、4、4.5、5、5.6、6.3、7.1、8、9、10、11、12.5、14、16、18、20、22、25、28、32、36、40、45、50、56、63、71、80、90、100、110、125、140、160、180、200、220、250、280、320。 b) Current time product deviation: ± (5% + 0.1 mAs) 5. Operating frequency: Maximum operating frequency 300kHz±20kHz。	5. Operating frequency: Maximum operating frequency 300kHz		

Functional requirements	1. Exposure technology mode The device should have mA/ms, mAs, mAs/ms modes. 2. Fault diagnosis and prompt 1) During the exposure process, release the handbrake actively, and an error should be prompted. 2) If the internal temperature of the oil tank of the combined head exceeds the limit, an error should be prompted.	1. Exposure technology mode The device should have mA/ms, mAs modes. 2. Fault diagnosis and prompt All filament currents display values. When the range is exceeded, the exposure is not allowed, a continuous alarm will sound and the value on the display will flash.	SE	User manual
Electrical safety	Shall comply with the requirements of IEC 60601-1 and IEC 60601-2-54.	Shall comply with the requirements of IEC 60601-1 and IEC 60601-2-54.	SE	User manual
EMC	Shall comply with the requirements of IEC 60601-1-2.	Shall comply with the requirements of IEC 60601-1-2.	SE	User manual
Software requirements	1. Basic data configuration 2. Exposure parameter setting	1. Basic data configuration 2. Exposure parameter setting	SE	User manual

	It should be able to operate the software to set the exposure mode, filament, tube voltage, tube current, loading time and current time product. 3. Information indication and fault prompt	It should be able to operate the software to set the exposure mode, filament, tube voltage, tube current, loading time and current time product. 3. Information indication and fault prompt		
Cybersecurity requirements	Data interface: There is an RS-232 output interface, and the RS-232 interface is used for the communication between the Combined High Frequency X-ray Source and the control software of the client X-ray imaging device to meet the interactive information.	None	Difference: 6) Cybersecurity requirements are different. The subject device have been tested and evaluated for cybersecurity. We have not found information related to cybersecurity about the predicate device.	User manual
Sterilization / disinfection method	Not applicable	Not applicable	Neither sterilization/disinfection is required.	/

There are 6 differences in comparison items between the subject device and the predicate device of the same type of medical devices:

Table 2 Comparative Analysis

No.	Different item	Difference description	Detailed description
1	Structural composition	The predicate device is accompanied with a mobile column with articulated arm and cassette basket, which the subject device does not have.	The subject device is an X-ray source which is a component of the X-ray system and does not require a mobile column with an articulated arm and a cassette basket. We sell the subject device to the complete machine manufacturers, and they might provide a mobile column with an articulated arm and a cassette basket, or other accessories according to their own needs.
2	Basic parameter	The maximum nominal electric power and the maximum output electric power in the model declared by the subject device are 5.6kW. While the maximum nominal electric power and the maximum output electric power in the model declared by the predicate device are 4kW.	The subject device has more models and various powers. There is only one model of the predicate for comparison, and the power data is single. The range of the subject device applied for is wider and applicable to more places and body parts.
3	Performance requirements	The number systems of tube current, loading time and current time product are different.	The distribution of the subject device is more than that of the predicate device, and the radiation dose received by patients is more accurate, so as to avoid the adverse impact of useless dose on

		The subject device is distributed according to the R’20 number system, and the predicate device is distributed according to the R'10 number system and the user-defined number system.	patients.
4		The loading time deviation of the subject device is larger than that of the predicate device. The deviation of the subject device is controlled within the scope of the international standard requirements.	The irradiation time of the subject device is 0.1ms longer than that of the predicate device during one exposure, which has no effect on the radiation dose received by the human body. The performance indicators of the subject device have been verified by third-party registration testing and meet the requirements of IEC 60601-1 and IEC 60601-2-54. This difference does not adversely affect the safety and efficacy of the product.
5		The regulation range of current time product of the subject device is larger than that of the predicate device.	The current time product range of the subject device is larger than that of the predicate device, and is applicable to a wider range of patient groups, body parts and places. The performance indicators of the subject device have been verified by third-party registration testing and meet the requirements of IEC 60601-1 and IEC 60601-2-54. This difference does not adversely affect the safety and efficacy of the product.

6	Cybersecurity requirements	The subject device have been tested and evaluated for cybersecurity. We have not found information related to cybersecurity about the predicate device.	The control software of the subject device is installed on the general computer platform and configured by the user. The user manual provides instructions for the installation, operation, uninstallation and other use of the control software. The software functions and cybersecurity requirements have been verified by internal tests and third-party registration tests to meet the requirements of clinical application of the product, which will not adversely affect the safety and effectiveness of the product.

Through the above comparative analysis, the differences between Combined High Frequency X-ray Source of our company and the predicate device will not affect the safety and effectiveness of the product.

VII. PERFORMANCE DATA

The following performance data were provided in support of the substantial equivalence determination.

Biocompatibility testing

N/A.

Electrical safety and electromagnetic compatibility (EMC)

Electrical safety and EMC testing were conducted on the Powersite device, consisting of shell case, control panel mounting assembly, DCDC riser mounting assembly, power panel mounting assembly, ESU energy storage capacitor mounting assembly, high voltage TANK, collimator, Lithium battery. The device complies with the IEC 60601-1, IEC 60601-1-3 and IEC 60601-2-54 standards for safety and the IEC 60601-1-2 standard for EMC.

Software Verification and Validation Testing

Software verification and validation testing were conducted and documentation was provided as recommended by FDA's Guidance for Industry and FDA Staff, "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices." The software for this device was considered as a "Moderate" level of concern, since a failure or latent flaw in the software could indirectly result in minor injury to the patient or operator through incorrect or delayed information or through the action of a care provider.

Mechanical and acoustic testing

- Acoustic Testing
- Elongation of the bending cable
- Crimp assembly, cable tensile strength, cable flexibility, minimum bending radius of the cables
- Simulated use testing

Animal Study

N/A.

Clinical Studies

Clinical images are not necessary to demonstrate substantial equivalence, based on the nature of the device (an x-ray generator) and on close similarities to the predicate system. Successful Bench Testing results should be sufficient to show device safety and effectiveness.

Summary

Based on the basic principle, intended use, performance parameters, operating environment, etc, Powersite Combined High Frequency X-ray Source was found to have a safety and effectiveness profile that is similar to the predicate device.

VIII. CONCLUSIONS

Since the subject device is an integral part of the X-ray imaging system, and similar products are mature and clinical-free products, substantial equivalence can be supported by comparing the basic principles, intended use, performance parameters, operating environment, etc. The

safety of the device is supported by non-clinical data, hardware and software verification and validation indicate that Powersite Combined High Frequency X-ray Source should perform as intended under the specified conditions of use. The performance of Powersite Combined High Frequency X-ray Source is equivalent to that of similar devices for the same intended use sold on the market at present.