DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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December 2, 2016

ORICH MEDICAL EQUIPMENT (TIANJIN) CO., LTD.
% Mr. Jun Peng
Principal Consultant
P&L Scientific, Inc.
6840 SW 45th Lane, Unit 5
MIAMI FL 33155

Re: K152813
Trade/Device Name: FS-500DDR Medical Radiographic X-Ray System
Regulation Number: 21 CFR 892.1680
Regulation Name: Stationary x-ray system
Regulatory Class: II
Product Code: KPR
Dated: September 26, 2016
Received: November 8, 2016

Dear Mr. Peng:

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)*

K152813

Device Name
FS-500DDR Medical Radiographic X-Ray System

Indications for Use *(Describe)*

FS-500DDR Medical Radiographic X-Ray System is designed to be used by a qualified/trained doctor or technician on adult and pediatric patients for taking diagnostic images 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.

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) summary of Safety and Effectiveness as required by the Safe Medical Devices Act of 1990 and codified in 21 CFR 807.92 upon which Substantial Equivalence is based:
The Assigned 510(k) Number is: k152813

1. Submitter Information:

- **Sponsor/510(k) Owner:**

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Date: September 26, 2016

- **510(k) Contact Name:**

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2. Device Name and Classification

Trade Name: FS-500DDR Medical Radiographic X-Ray System
Common Name: Direct Digital Radiographic X-Ray System
Classification Name: Stationary X-Ray System, Product code 90 KPR
Classification: 21 CFR 892.1680, Class II
Product code: KPR

4. Predicate Devices:

Manufacturer Name	GE Medical Systems, Inc.	Orich Medical Equipment (Tianjin) Co., Ltd.
Regulation Number	K012389	K120034
Trade Name	GE Revolution XR/*d* Digital Radiographic Imaging System	DF-211H Radiographic X-Ray System
Common Name	System, X-Ray, Stationary	System, X-Ray, Stationary
Classification Name	Stationary X-Ray System	Stationary X-Ray System
Classification Number	21 CFR 892.1680	21 CFR 892.1680
Product Code	KPR	KPR
Date of Clearance	Aug. 10, 2001	Apr. 17, 2012

5. Description of Device

The FS-500DDR is a Medical Radiographic X-Ray System with digital radiography (DR) technology. It is consisting of a high voltage generator, control console, X-Ray tube assembly, collimator, UC bracket or Rail suspension assembly, solid-state X-Ray flat panel detector, work station and radiographic table. This product is applicable to clinical diagnostic radiography in all hospitals whether large or small. It is applicable to the radiography of various parts of human body. It can also be used in scientific research and education of medical scientific research institutes and medical colleges. Power supply requirements: three phase: 380Vac, 50Hz/60Hz; fluctuation range for voltage: 10%; the power source capacity: 50kVA, the range of tube voltage is 40-150kV, with current 10-630mA. The time range of exposure is 1ms-10s, the range of mAs is 0.1-630mAs.

There are two types of configuration (1001-1002) for FS-500DDR; the difference is for the mounting of the X-ray tube. For X-ray tube mounting the configuration is either the UC arm or Rail suspension assembly.

Table 1-1 Components of FS-500DDR (1001)

Component	Model	Manufacturer
Digital image acquisition and processing system	FU-800CCS	Orich Medical Equipment (Tianjin)Co., Ltd.
Medical monitor	RTV-5	Orich Medical Equipment (Tianjin)Co., Ltd.
High-voltage generator	HK801-1(50kW)	Orich Medical Equipment (Tianjin)Co., Ltd.
X-ray tube assembly	DX7254/150	Orich Medical Equipment (Tianjin)Co., Ltd.
X-ray tube	E7843	Toshiba Electron Tubes and Devices Co., Ltd.
Flat panel detector	FDX4343R	Toshiba Electron Tubes and Devices Co., Ltd.
UC arm	FSU-I	Orich Medical Equipment (Tianjin)Co., Ltd.
Mobile radiographic patient table	YDC-I	Orich Medical Equipment (Tianjin)Co., Ltd.
Beam limiting device	S/DS-2	Orich Medical Equipment (Tianjin)Co., Ltd.

Table 1-2 Components of FS-500DDR (1002)

Component	Model	Manufacturer
Digital image acquisition and processing system	FU-800CCS	Orich Medical Equipment (Tianjin)Co., Ltd.
Medical monitor	RTV-5	Orich Medical Equipment (Tianjin)Co., Ltd.
High-voltage generator	HK801-1(50kW)	Orich Medical Equipment (Tianjin)Co., Ltd.
X-ray tube assembly	DX7254/150	Orich Medical Equipment (Tianjin)Co., Ltd.
X-ray tube	E7843	Toshiba Electron Tubes and Devices Co., Ltd.
Flat panel detector	FDX4343R	Toshiba Electron Tubes and Devices Co., Ltd.
Rail suspension assembly	FSU-III	Orich Medical Equipment (Tianjin)Co., Ltd.
Elevating photography table	DFY-III	Orich Medical Equipment (Tianjin)Co., Ltd.

Beam limiting device	S/DS-2	Orich Medical Equipment (Tianjin)Co., Ltd.

6. Intended Use

FS-500DDR Medical Radiographic X-Ray System is designed to be used by a qualified/trained doctor or technician on adult and pediatric patients for taking diagnostic images 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.

7. Comparison of Technological Characteristics

The FS-500DDR Medical Diagnostic X-Ray system is similar to the predicate devices:

- Has the same intended use and indications for use
- Utilizes the same operating principle
- Incorporates the same basic design
- Incorporates the same technological characteristics
- Tested to the same electrical and electromagnetic safety standards for medical electrical equipment
- Manufactured under a quality system

The differences between the subject devices and predicate devices:

- The subject device utilizes a lower frequency X-ray generator which does not raise any level of safety concern and affect any effectiveness; the generator frequency does affect the X-ray exposure parameters.
- The subject device utilizes a radiographic table with smaller weight capacity which does not raise any level of safety concern and affect any effectiveness.
- The inherent filtration for the collimator in the subject device is different from the predicate device; this difference does not affect the safety and effectiveness.
- The subject device utilizes a different X-Ray flat panel detector, however, both the bench and clinical test demonstrate that does not raise the level of safety concern and affect any effectiveness.

8. Summary Performance Data

- EN 60601-1 Medical electrical equipment - Part 1: General requirements for basic safety and essential performance 2006 + AC:2010
- EN 60601-1-2:2007 (Third Edition, 2007), Medical Electrical Equipment - Part 1-2: General Requirements for Safety - Collateral Standard: Electromagnetic
- IEC 60601-2-7:1998 Medical electrical equipment –Part 2-7: Particular requirements for the safety of high-voltage generators of diagnostic X-ray generators
- IEC 60601-2-28:2010 Medical electrical equipment - Part 2-28: Particular requirements for the basic safety and essential performance of X-ray tube assemblies for medical diagnosis
- IEC 60601-2-54:2009 - Medical electrical equipment - Part 2-54: Particular requirements for the basic safety and essential performance of X-ray equipment for radiography and radioscopy
- IEC 60601-1-3:2008 Medical electrical equipment - Part 1: General requirements for safety - 3. Collateral standard: General requirements for radiation protection in diagnostic X-ray equipment + AC2010

- ISO 10993-5:1999: Biological evaluation of medical devices -- Part 5: Tests for In Vitro cytotoxicity
- ISO 10993-10:2002, Biological evaluation of medical devices - Part 10: Tests for irritation and delayed-type hypersensitivity
- ISO 10993-1:2009 Biological Evaluation of Medical Devices Part 1: Evaluation and Testing
- Clinical concurrence study of images pairs to demonstrate the equivalent diagnostic capability

9. Conclusion

After analyzing both bench and external laboratory testing data, including electrical safety, mechanical safety and EMC compliance, the intended use and supporting data can conclude that the device in the submission is safe and effective as the predicate devices.