K120034

ORICH MEDICAL EQUIPMENT (TIANJIN) CO., LTD.

APR 17 2012

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: _____

1. Submitter Information:
   - **Sponsor/510(k) Owner:**
     ORICH MEDICAL EQUIPMENT (TIANJIN) CO., LTD.
     No. 16 Cuiming Road YAT-SEN Scientific Industrial Park,
     Tianjin Economic Technological Development Area, Tianjin 301726, China
     Phone: +86 22 8216 1240 Fax: +86 22 8216 0813

     Dated: December 28, 2011

   - **510(k) Contact Name:**
     Mr. Jun Peng
     P&L SCIENTIFIC, INC.
     6840 SW 45TH LN #5
     MIAMI, FL 33155
     Phone: (305) 609 4701 Fax: (305) 397 0289
     Email: jpeng@plscientificinc.com

2. **Device Name**
   Trade Name: DF-211H Radiographic X-Ray system
   Common Name: System, X-Ray, Stationary
   Classification Name: Stationary X-Ray System

3. **Classification:**
   Classification: 21 CFR 892.1680; Class II
   Product Code: KPR

4. **Predicate Devices:**

Model HF-50R Computer Controlled X-Ray System	K052541	AVANT Medical Systems

5. **Description of Device**
   The DF-211H Radiographic X-Ray system is complete, consisting of a 50kW X-Ray generator, control console, X-Ray tube assembly, collimator, and radiographic table. This product is applicable to clinical diagnostic radiography in all hospitals whether large or small. It has functions such as general radiography, anatomic program radiography (APR), etc. It has option of ionization chamber automatic exposure control (AEC). 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: 380V, 50Hz; single phase: 120V, 60 Hz; fluctuation range for voltage: 10%; the power source capacity: 50kW.

6. Intended Use

DF-211H 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 DF-211H radiographic 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

8. Summary Performance Data

- IEC 60601-1 Medical electrical equipment - Part 1: General requirements for basic safety and essential performance, 1988; Amendment 1, 1991-11, Amendment 2, 1995. (General)
- 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 (GB 9706.3-2000 idt) Medical electrical equipment –Part 2-7: Particular requirements for the safety of high-voltage generators of diagnostic X-ray generators
- IEC 60601-2-28:1993 (GB 9706.11-1997 idt) Medical electrical equipment - Part 2-28: Particular requirements for the basic safety and essential performance of X-ray tube assemblies for medical diagnosis
- IEC 60601-1-3:1994 (GB 9706.12-1997 idt) Medical electrical equipment - Part 1: General requirements for safety - 3. Collateral standard: General requirements for radiation protection in diagnostic X-ray equipment
- IEC 60601-2-32:1994 (GB 9706.14-1997 idt) Medical electrical equipment - Part 2-32: Particular requirements for the safety of associated equipment of X-ray equipment

9. Conclusion

After analyzing both bench and external laboratory testing data, the intended use and supporting data can conclude that the device in the submission is safe and effective as the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

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

APR 17 2012

Orich Medical Equipment (Tianjin) Co., Ltd.
% Mr. Jun Peng
Principal Consultant
P&L Scientific, Inc.
6840 SW 45th Lane #5
MIAMI FL 33155

Re: K120034
Trade/Device Name: DF-211H Radiographic X-Ray System
Regulation Number: 21 CFR 892.1680
Regulation Name: Stationary x-ray system
Regulatory Class: II
Product Code: KPR
Dated: March 2, 2012
Received: March 7, 2012

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.

If your device is classified (see above) into class II (Special Controls), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. 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 Parts 801 and 809); medical device reporting (reporting of

medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Parts 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. 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 Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely Yours,

Janine M. Morris
Acting Director
Division of Radiological Devices
Office of In Vitro Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K120034

Device Name: DF-211H Radiographic X-Ray System

Indications for Use:

DF-211H 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.

Prescription Use __✓____ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

(Division Sign-Off)
Division of Radiological Devices
Office of In Vitro Diagnostic Device Evaluation and Safety

510K K120034