JUN 29 2009

K083640

510(k) Summary

This summary of 510(k) safety and effectiveness information is being submitted in accordance with requirements of 21 CFR Part 807.92.

Date: Nov. 18, 2008

1. Company and Correspondent making the submission:

Name – CHOONGWAE MEDICAL CORPORATION
Address – 698, Shingdaebang-Dong, Dongjak-Gu, Seoul, Korea
Telephone – +82-2-285-6950
Fax – +82-2-286-3007
Contact – Mr. Dong Un, Shin
Internet – http://www.cwm.co.kr/

2. Device :

Trade/proprietary name	: CXD-DR80D
Common Name	: Digital X-ray Imaging System
Classification Name	: System, x-ray, stationary

3. Predicate Device :

Manufacturer	: General Electric Company
Device	: Revolution XR/d
510(k) Number	: K012389 (Decision Date - Aug. 10. 2001)
Manufacturer	: DRTECH Co., Ltd.
Device	: FLAATZ 750
510(k) Number	: k080064 (Decision Date - Jan. 23. 2008)

4. Classifications Names & Citations :

21CFR 872.1680, KPR, System, x-ray, stationary, Class2

5. Description :

5.1 General

The digital X-ray imaging system consists of a high voltage (HV) generator, a tube support unit, an X-ray beam limiting device, a wall stand unit, a bucky table unit, a detector, operating software, and a tube, operates on a high-frequency inverter method, and is primarily used in a hospital for diagnosis of diseases in skeletal, respiratory and urinary systems.

5.2 Product features

Rated voltage from external power supply is introduced into the X-ray control device, and the tube voltage, tube current and time are set up. When an X-ray radiation command is given, the preset voltage is applied to the primary side of the high voltage generator and a high voltage to produce X-ray is generated from the secondary side.

When this high voltage is applied to the X-ray tube, it strikes substance named target and X-ray is generated. This X-ray passes part of a human body to be diagnosed.

Electric charges are collected by electrodes located at each pixel, and outputted to the image processing unit through the thin film transistor (TFT) array. Amplification and digital data conversion take place in the image processing unit, and the data that has been transmitted to the workstation (image processing computer) through a cable is stored in medical standard DICOM files by operating software. Stored images are used for image analysis after transmitted to the picture archiving and communication system (PACS) by operating software.

The detector which is used proposed device is FLAATZ 750 of DRTECH Co., Ltd..

This detector is cleared by FDA 510(k) (k080064).

5 Indication for use :

The CXD-DR80D Digital X-ray Imaging System is indicated for use in generating radiographic images of human anatomy. This device is not intended for mammographic applications.

The CXD-DR80D X-ray Imaging System utilizes the FLAATZ 750 detector, manufactured by DRTECH.

6 Comparison with predicate device :

CHOONGWAE MEDICAL CORPORATION, believes that the CXD-DR80D is substantially equivalent to the Revolution XR/d of General Electric Company and FLAATZ 750 of DRTECH Co., Ltd..

7 Safety, EMC and Performance Data :

Electrical, mechanical, environmental safety and performance testing according to standard EN/IEC 60601-1, EN/IEC 60601-1-1, EN/IEC 60601-1-3, EN/IEC 60601-2-7, EN/IEC 60601-2-28 and EN/IEC 60601-2-32 was performed, and EMC testing was conducted in accordance with standard EN/IEC 60601-1-2(2001). All test results were satisfactory.

9. Conclusions :

In accordance with the Federal Food, Drug and Cosmetic Act, 21 CFR Part 807 and based on the information provided in this premarket notification CHOONGWAE MEDICAL CORPORATION concludes that The CXD-DR80D is safe and effective and substantially equivalent to predicate devices as described herein.

10. CHOONGWAE MEDICAL CORPORATION will update and include in this summary any other information deemed seasonably necessary by the FDA.

END

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 29 2009

CHOONGWAE Medical Corporation
% Mr. Charles Mack
Principle Engineer
International Regulatory Consultants
77325 Joyce Way
ECHO OR 97826

Re: K083640
Trade/Device Name: Digital X-ray Imaging Systems/CXD-DR80D
Regulation Number: 21 CFR 892.1680
Regulation Name: Stationary x-ray system
Regulatory Class: II
Product Code: KPR
Dated: May 3, 2009
Received: May 15, 2009

Dear Mr. Mack:

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 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 go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 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/cdrh/mdr/ 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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Janine M. Morris
Acting Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number(if known): K083640

Device Name: Digital X-ray Imaging System /CXD-DR80D

Indications for Use:

The CXD-DR80D Digital X-ray Imaging System is indicated for use in generating radiographic images of human anatomy. This device is not intended for mammographic applications.

The CXD-DR80D Digital X-ray Imaging System utilizes the FLAATZ 750 Detector, manufactured by DRTECH Co. (K080064)

Prescription Use ✓ AND/OR Over-The-Counter Use _____

(Part 21 CFR 801 Subpart D) (Part 21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation(ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal and Radiological Devices
510(k) Number K083640