K101779

510 (k) Summary

MAY 16 2011

October 12, 2010

1. Company and Correspondant Making the Submission:

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Contact: John Lim
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2. Identification of Device

Classification Name: Stationary X-ray System
Common Name: Digital Radiography X-ray System
Trade/Proprietary Name: Clear Vision DR 2000

3. Predicate Device

Manufacturer:	Choongwae Medical Corporation
Device:	CXD-DR80D
510(k) Number:	K083640 (Decision Date Jul 29, 2009)

Manufacturer:	Vieworks Co., Ltd
Device:	QXR 9
510(k) Number:	K073056 (Decision Date Nov 13, 2007)

Manufacturer:	Vieworks Co., Ltd
Device:	QXR 16
510(k) Number:	K080553 (Decision Date Apr 16, 2008)

4. Product Classification Names and Citations

Regulatory Number:	21 CFR 892.1680
Regulatory Class:	II
Product Code:	90 KPR

5. Description:

The Clear Vision DR2000 system is a high-resolution digital imaging system designed for digital radiography. It is designed to replace conventional film

radiography techniques. This system consists of a tube head/collimator assembly mounted on a U-Arm, along with a generator, generator control, and a detector, operating software.

The detector which is used proposed device is QXR9 (K073056) and QXR16 (K080553) of Vieworks Co., Ltd. These detectors are cleared by FDA 510(k).

6. Indication for use

The Clear Vision DR 2000 product is 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.

The Clear Vision DR 2000 system is intended to be used in medical clinics and hospitals for emergency, orthopedic, chiropractic, and other medical purposes.

7. Comparison with Predicate Device:

JUNGWON PRECISION IND. CO., LTD, believes that the Clear Vision DR2000 is substantially equivalent to the CDX-DR80D of Choongwae Medical Corporation and QXR 9, QXR 16 of Vieworks Co., Ltd.

8. 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(2007). 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 JUNGWON PRECISION IND. concludes that Clear Vision DR 2000 is safe and effective and substantially equivalent to predicate devices as described herein.

10. JUNGWON PRECISION IND. CO., LTD. will update and include in this summary any other information deemed seasonably necessary by the FDA.

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

JPI Healthcare Co., Ltd.
% Mr. William Little
Product Specialist
JPI Healthcare Solutions, Inc.
52 Newtown Plaza
PLAINVIEW NY 11803

MAY 16 2011

Re: K101779
Trade/Device Name: Clear Vision DR 2000/Digital Radiography X-Ray System
Regulation Number: 21 CFR 892.1680
Regulation Name: Stationary x-ray system
Regulatory Class: II
Product Code: KPR
Dated: April 5, 2011
Received: April 7, 2011

Dear Mr. Little:

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,

Mary S Pastel

Mary S. Pastel, Sc.D.
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):

Device Name: Clear Vision DR 2000 / Digital Radiography X-ray System

Indications for Use:

The Clear Vision DR 2000 product is 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.

The Clear Vision DR 2000 system is intended to be used in medical clinics and hospitals for emergency, orthopedic, chiropractic, and other medical purposes. This device is not indicated for use in mammography.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _N/A____ (21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Mary S Pastel

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

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