K092830

510(k) Summary

JUL 21 2010

Date: July 27, 2009

1. Submitter:

Company Name	: Vatech Co., Ltd.
Company Address	: 23-4, Seogu-Dong, Hwaseong-si, Gyeonggi-do, 445-170, Korea
U.S. Agent Address:	333 Meadowlands Parkway, #303 Secaucus, NJ 07094
Contact Person	: Dave Kim
Telephone	: (832)-623-2099
Fax	: (713)-464-8880

2. Device :

Reason for 510(k)	:New Model
Manufacturer	: Vatech Co., Ltd.
Model Name:	: DRC-1000
Common Name	: Digital X-ray imaging system
Classification Name	: SYSTEM, X-RAY, STATIONARY

3. Predicate Device :

Manufacturer	: Sedecal, Inc.
Model Name	: Sedecal X-Plus LP Plus Digital
Classification Name	: SYSTEM, X-RAY, STATIONARY
510(k) Number	: K090238 (Decision Date - Feb. 27. 2009)

4. Classifications Names & Citations :

21CFR 892.1680, KPR, System, X-ray, Stationary, Class2

5. Description :

5.1 General

DRC-1000 is a digital diagnostic x-ray system which consists of Solid State Xray Imager (Flat Panel), tube-collimator assembly mounted on a U-Arm, generator and operation control unit. DRC-1000 is designed for adult and pediatric subjects for taking diagnostic exposures of the skull, spinal column, chest, extremities and other body parts. Applications can be performed with the patient sitting, standing, or lying in the prone or supine position.

5.2 Product features

a. Condition of Input

1-1. Rated input voltage : AC 220V / AC 110V

1-2. Guaranteed working voltage

1) 110V Mode : 100 ~120V

2) 220V Mode : 200 ~240V

1-3. Possible working voltage

1) 110V Mode : 90 ~130V

2) 220V Mode : 180 ~ 250V

1-4. Rated input frequency : 50Hz/60Hz

1-5. Insulation withstanding : below than 1.5KV cap for more than one minute between first test and second test.

b. Capture Mode

Whole body

Shooting Mode : CHEST/RIB/STERNUM/APEX/SELLA..

6. Indication for use :

Digital X-ray Imaging System, DRC-1000, 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, extremities, and other body parts.
Not to be used for fluoroscopy, angiography, or screening mammography. Applications can be performed with the patient sitting, standing, or lying in the prone or supine position.

7. Comparison with predicate device :

Vatech Co., Ltd., believes that the DRC-1000 is substantially equivalent to the Sedecal X-Plus LP Plus Digital of Sedecal, Inc.

8. Safety, EMC and Performance Data :

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

9. Conclusion :

In accordance with the Federal Food, Drug and Cosmetic Act, 21 CFR Part 807 and based on the information provided in this premarket notification Vatech Co., Ltd. concludes that The DRC-1000 is safe and effective and substantially equivalent to predicate devices as described herein.

10. Vatech Co., Ltd. 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
10903 New Hampshire Avenue
Document Control Room – WO66-G609
Silver Spring, MD 20993-0002

Vatech Co., Ltd.
% Mr. Dave Kim
Medical Device Regulatory Consultant
Vatech America
333 Meadowlands Parkway, #303
SECAUCUS NJ 07094

JUL 21 2010

Re: K092830
Trade/Device Name: Digital X-ray Imaging System / DRC-1000
Regulation Number: 21 CFR 892.1680
Regulation Name: Stationary x-ray system
Regulatory Class: II
Product Code: KPR
Dated: January 14, 2010
Received: January 19, 2010

Dear Mr. Kim:

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,

Donald J. St.Pierre
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): K092830

Device Name: Digital X-ray Imaging System / DRC-1000

Indications for Use:

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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 (CDRH)~~ OIVD

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

510K K092803