K073056
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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: Aug. 31, 2007

NOV 1 3 2007

1. Company and Correspondent making the submission:

Name – Vieworks Co., Ltd.
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Telephone – +82-70-7011-6190
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Contact – Raza, Kim / Sales & Marketing Manager
E-mail – lukekim@vieworks.com

2. Device :

Trade/proprietary name	: QXR-9
Common Name	: Digital Radiography System
Classification Name	: Solid State X-ray Imaging Device

3. Predicate Devices :

Manufacturer	: IMAGING DYNAMICS COMPANY LTD.
Device	: XAMINER
510(k) Number	: K061595(Decision Date – 8. 17. 2006)
Manufacturer	: Swissray International, Inc.
Device	: AddOn Multi System
510(k) Number	: K973710(Decision Date – 12. 18. 1997)

4. Classifications Names & Citations :

21CFR 892.1650, MQB - Solid State X-ray Imaging Device, Class 2

5. Description :

5.1 General

The QXR-9 Digital Radiography Systems is a high-resolution digital imaging system designed for digital radiography. It is designed to replace conventional film radiography techniques. This system consists of Detector, Power Supply Unit, Accessories, and S/W. The S/W is operated at a workstation that is using Windows XP based OS as its operating system.

The system allows the operator to acquire and display images(Image size : 3072x3072 pixels) on 1600 x1200 high resolution monitor.

Various features of S/W such as image inversion, image processing, zooming, panning, window level adjustment, contrast adjustment etc enable the operator to view diagnostic details difficult to see using conventional non-digital techniques.

5.2 Features

- One Charge Coupled Device (CCD) armed with one lens.
- 17" x17" imaging area with 3072 x 3072 image format.
- High resolution image with 3.5lp/mm
- Wide dynamic range with 14-bit digitization
- S/W is designed to be operated on MS Windows XP operating system
- Image process parameters are selectable according to the body part to make best images for diagnosis
- Make copy of images to a CD or DVD or an external USB storage
- No x-ray generator control
- DICOM3.0 standard compliance
- DICOM printer and laser printer compatible
- Image Acquisition within 3.5 seconds after x-ray exposure
- Display processed image within 10 seconds after x-ray exposure
- Non-Processed image can be displayed by using Preview function

6. Indication for use :

QXR-9 Digital Radiography system is indicated for digital imaging solution designed for general radiographic system for human anatomy. It is intended to replace film or

screen based radiographic systems in all general purpose diagnostic procedures. Not to be used for mammography.

7. Comparison with predicate device :

Vieworks Co., Ltd. believes that the Digital Radiography System (QXR-9) is substantially equivalent to to Xaminer of IMAGING DYNAMICS COMPANY LTD. and AddOn Multi System of Swissray International, Inc..

8. Safety, EMC, Biocompatibility and Performance Data :

Electrical, mechanical, environmental safety and performance testing according to standard IEC 60601-1 and IEC 60601-1-1 was performed, and EMC testing was conducted in accordance with standard IEC 60601-1-2(2001).

Biocompatibility testing was conducted in accordance with Standard ISO 10993-1.

Non-clinical & Clinical considerations according to FDA Guidance 및uidance for the Submission of 510(k)뭘for Solid State X-ray Imaging Devices?was performed.

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 Vieworks Co., Ltd. concludes that the Digital Radiography System(QXR-9) is safe and effective and substantially equivalent to predicate devices as described herein.

10. Vieworks 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

Viewworks Co., Ltd
% Mr. Morten Simon Christensen
Staff Engineer/Office Coordinator
Underwriters Laboratories, Inc.
455 E. Trimble Road
SAN JOSE CA 95131-1230

AUG 23 2013

Re: K073056
Trade/Device Name: Digital Radiography System/QXR-9
Regulation Number: 21 CFR 892.1680
Regulation Name: Stationary x-ray system
Regulatory Class: II
Product Code: MQB
Dated: October 15, 2007
Received: October 30, 2007

Dear Mr. Christensen:

This letter corrects our substantially equivalent letter of November 13, 2007.

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): K073056

Device Name: Digital Radiography System/ QXR-9

Indications for Use:

QXR-9 Digital Radiography system is indicated for digital imaging solution designed for general radiographic system for human anatomy. It is intended to replace film or screen based radiographic systems in all general purpose diagnostic procedures. Not to be used for mammography.

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 K073056