K122866

510(k) Summary

JAN 11 2013

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

Date: SEP. 11, 2012

Company and Correspondent making the submission:

Name – Vieworks Co., Ltd.

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Telephone – +82-70-7011-6176

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Contact – Ms. Sungwhie Kim

Internet – http://www.vieworks.com

Proposed Device :

Trade/ Proprietary Name	: ViVIX-S with VXvue
Classification Name	: Solid State X-ray Imager
Product Code	: MQB
Device Class	: 2
Regulation Number	: 892.1680

Predicate Device :

Manufacturer	: Vieworks Co., Ltd.
Trade/ Proprietary Name	: ViVIX-S
Classification Name	: Solid State X-ray Imager
Product Code	: MQB
Device Class	: 2
510(k) Number	: K120020

Description:

ViVIX-S with VXvue is a digital X-ray flat panel detector which has 43x43cm (FXRD-1717SA, FXRD-1717SB) or 35.8x43cm (FXRD-1417SA, FXRD-1417SB) imaging area.

The device intercepts x-ray photons and the scintillator emits visible spectrum photons that illuminate an array of photo (a-SI)-detectors that create an electrical signals. After the electrical signals are generated, it is converted to digital value, and the images will be displayed on monitors.

This device should be integrated with an operating PC and an X-Ray generator to utilize as digitalizing X-ray images and transfer for radiography diagnostic. Advanced digital imaging process allows considerably efficient diagnosis, all kind of information management, and sharing of image information on network.

Intended use:

ViVIX-S with VXvue 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.

Comparison with predicate device:

The imaging principle, intended use, technology and materials of ViVIX-S with VXvue are substantially equivalent to the predicate device, ViVIX-S of Vieworks Co., Ltd. for the specified indications and satisfy the FDA regulatory requirements for a 510(k).

Safety, EMC and Performance Data:

- Electricl safety and EMC testing

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

- Non-clinical study

The following non-clinical studies have been performed and the results show that the ViVIX-S with VXvue is substantially equivalent to the predicate devices in the

market.

-Detective quantum efficiency(DQE), Quantum limited performance, Modulation transfer function(MTF), Effects of aliasing, Sensitivity linearity, Lag(Erasure thoroughness), Change in detection sensitivity, Dose requirement and reciprocity changes, Stability of device characteristics with time, Uniformity of device characteristic, Noise power spectrum(NPS), Spatial resolution, Minimum dose, Image Acquisition time, & Black level.

▪ Clinical study

A concurrence study of 30 clinical images was conducted to compare the performance of the ViVIX-S with VXvue to the predicate device (K120020). There were no significant differences between the images of the ViVIX-S with VXvue and the predicate device images.

Conclusions :

Based on the result of the non-clinical and the clinical study performed, we conclude that the ViVIX-S with VXvue is safe, effective, and substantially equivalent to the predicate devices.

END

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-002

January 11, 2013

Vieworks Co., Ltd.
C/O Ms. Priscilla Chung
Regulatory Affairs Consultant
951 Starbuck St. Unit J
FULLERTON CA 04300

Re: K122866
Trade/Device Name: ViVIX-S with VXvue
Regulation Number: 21 CFR 892.1680
Regulation Name: Stationary x-ray system
Regulatory Class: II
Product Code: MQB
Dated: November 26, 2012
Received: November 29, 2012

Dear Ms. Chung:

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

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/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/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Sean M. Boyd -S for

Janine M. Morris
Director, Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K122866

Device Name: ViVIX-S with VXvue

Indications for Use:

ViVIX-S with VXvue 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 and/or for fluoroscopy.

Prescription Use __X____ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of *In Vitro* Diagnostics and Radiological Health (OIR)

Sean M. Boyd -S

(Division Sign Off)
Division of Radiological Health
Office of *In Vitro* Diagnostic and Radiological Health

510(k) K122866