DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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February 26, 2016

Vieworks Co., Ltd.
% Ms. Priscilla Chung
Regulatory Affairs Consultant
LK Consulting Group USA, Inc.
2651 E. Chapman Avenue, Suite 110
FULLERTON CA 92831

Re: K152855
Trade/Device Name: VIVIX-S 1012N
Regulation Number: 21 CFR 892.1680
Regulation Name: Stationary x-ray system
Regulatory Class: II
Product Code: MQB
Dated: January 28, 2016
Received: February 2, 2016

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 contact the Division of Industry and Consumer Education 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. 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 Industry and Consumer Education 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,

Michael D. O'Hara For

Robert Ochs, Ph.D.
Director
Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K152855

Device Name
VIVIX-S 1012N

Indications for Use *(Describe)*
VIVIX-S 1012N (FXRD-1012NA, FXRD-1012NB, FXRD-1012NAW and FXRD-1012NBW) is indicated for digital imaging solution designed as a general radiographic system for human anatomy. It is intended to replace film or screen based radiographic systems in all general purposes of diagnostic procedures. It is not to be used for mammography.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

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510(k) Summary

[As required by 21 CFR 807.92]

(K152855)

This 510(k) summary of safety and effectiveness information is prepared in accordance with 21 CFR807.92

1. Date Prepared [21 CFR 807.92(a) (1)]

01/28/2016

2. Submitter's Information [21 CFR 807.92(a) (1)]

Name of Sponsor:	Vieworks Co., Ltd.
Address:	(Gwanyang-dong) 41-3,Burim-ro 170beon-gil,Dongan-gu, Anyang-si, Gyeonggi-do, 431-060 Republic of Korea
Contact Name:	Im, Yoonjae / RAQA team Manager
Registration Number:	3006013411
Name of Manufacturer:	Same as Sponsor

3. Trade Name, Common Name, Classification [21 CFR 807.92(a) (2)]

Trade Name:	VIVIX-S 1012N
Model Name:	FXRD-1012NA FXRD-1012NB FXRD-1012NAW FXRD-1012NBW
Common Name:	Digital Flat Panel X-ray Detector
Classification Name:	Stationary X-ray System
Classification Panel:	Radiology
Classification Regulation:	21 CFR 892.1680
Product Code:	MQB
Device Class:	2

4. Identification of Predicate Device(s) [21 CFR 807.92(a) (3)]

Primary Predicate Device:

- **510(k) Number: K122866**

Product Code:	MQB
Applicant:	Vieworks Co., Ltd.
Trade Name:	ViVIX-S with VXvue

Model Name: FXRD-1417SA
FXRD-1417SB
FXRD-1717SA
FXRD-1717SB
Decision Date: 01/11/2013

Reference Predicate Device

- **510(k) Number: K122865**
  Product Code: MQB
  Applicant: Vieworks Co., Ltd.
  Trade Name: ViVIX-S Wireless
  Model Name: FXRD-1417WA
  FXRD-1417WB
  Decision Date: 02/01/2013

5. Description of the Device [21 CFR 807.92(a) (4)]

o General Description

Models FXRD-1012NA, FXRD-1012NB, FXRD-1012NAW and FXRD-1012NBW intercept 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, these are converted to a digital value, and an image will be displayed on the monitor.
These devices should be integrated with an operating PC and an X-Ray generator to digitalize X-ray images and transfer the digitalized images for radiography diagnostic.
Advanced digital image processing allows considerably efficient diagnosis, all kinds of information management, and image information sharing on the network.

o Differences between models

Models FXRD-1012NA, FXRD-1012NB, FXRD-1012NAW and FXRD-1012NBW are digital X-ray flat panel detectors, and each model has a 10 x 12 inch imaging area.
FXRD-1012NA and FXRD-1012NB communicate by using a wired communication feature (Giga-bit Ethernet communication method by connecting to a tether cable), while FXRD-1012NAW and FXRD-1012NBW communicate by using a wireless communication feature (IEEE 602.lla/b/g/n).
The scintillator used in FXRD-1012NA and FXRD-1012NAW is CsI. Gadox was used for FXRD-1012NB and FXRD-1012NBW.

The FXRD-1012N series is designed to be used with any certified X-ray generators that features DR Trigger mode and is marketed legally. When the DR Trigger mode is not desired, then the connection with the generator can be maintained with AED mode. FXRD-1012N is not designed to function as an X-ray control. The AED mode does not require integration procedure since there is no connection requirement between the X-ray System and the detector. The subject device can receive any types of x-ray signals without SW.

For the DR Trigger mode, the generator interface cable connects the SCU and the X-ray generator. The head of the cable is connected with one of the port (EXT-INF) of the SCU, and the other end of the cable (which is stripped) is connected to the generator's socket.

6. Intended Use [21 CFR 807.92(a)(5)]

VIVIX-S 1012N (FXRD-1012NA, FXRD-1012NB, FXRD-1012NAW and FXRD-1012NBW)is indicated for digital imaging solution designed as a general radiographic system for human anatomy. It is intended to replace film or screen based radiographic systems in all general purposes of diagnostic procedures. It is not to be used for mammography.

7. Technological Characteristics [21 CFR 807.92(a) (6)]

Comparisons with the predicate, devices show the technological characteristics of the proposed FXRD-1012NA, FXRD-1012NB, FXRD-1012NAW and FXRD-1012NBW devices to be substantially equivalent to the predicate devices. The proposed devices are functionally identical to the predicate devices.

8. Substantial Equivalence [21 CFR 807.92(b)(1) and 807.92]

When compared to the predicate devices (K122865 andK122866),the FXRD-1012NA, FXRD-1012NB, FXRD-1012NAW and FXRD-1012NBW presented in this submission have the same:

- Intended Use
- Technological characteristics
- Operating principle
- Design features
- Communication Method
- ScintillatorMaterials
- Resolution

There are similar performance characteristics as follow.

- Performance (MTF)
- Performance (DQE)

There are no significant difference between the FXRD-1012NA, FXRD-1012NB, FXRD-1012NAW and FXRD-1012NBW and the predicate devices that would adversely affect the use of the product. It is substantially equivalent to these devices in design, function, materials, operational principles and intended use.

Parameter	Reference Predicate Devices	Primary Predicate Devices	Subject Device
510(k) Number	K122865	K122866	K152855
Manufacturer	Vieworks Co., Ltd.		
Model Name	FXRD-1417WA, FXRD-1417WB	FXRD-1417SA, FXRD-1417SB, FXRD-1717SA,	FXRD-1012NA, FXRD-1012NB, FXRD-1012NAW,

			FXRD-1717SB	FXRD-1012NBW
Common Name		Digital Flat Panel X-ray Detector		
Classification Name		Solid State X-Ray Imager (Flat Panel/Digital Imager)		
Classification Panel		Radiology		
Classification Regulation		21 CFR 892.1680		
Product Code		MQB		
Device Class		2		
Intended Use		The ViVIX-S Wireless is indicated for digital imaging solution designed as a general radiographic system for human anatomy. It is intended to replace film or screen based radiographic systems in all general purposes of diagnostic procedures. It is not to be used for mammography.	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.	FXRD-1012NA, FXRD-1012NB, FXRD-1012NAW and FXRD-1012NBW are indicated for digital imaging solution designed as a general radiographic system for human anatomy. It is intended to replace film or screen based radiographic systems in all general purposes of diagnostic procedures. It is not to be used for mammography.
Design	Panel Shape	Square Panel	Square Panel	Square Panel
	Field of View	14 x 17inch	14 x 17inch 17 x 17inch	10 x 12inch
	Dimensions (H x W x D)	444 x 460 x15mm	444 x 460 x15 mm 470 x 470x 35mm	287.0 x 350.0 x 15.0mm
	Pixel Pitch	0.14mm	0.14mm	0.124mm
Materials Scintillator		CsI: TI, Gd2O2S:Tb	CsI: TI, Gd2O2S:Tb	CsI: TI, Gd2O2S:Tb
Performance	DQE 0.5 lp/mm 1 lp/mm 2 lp/mm 3 lp/mm	-	CsI 59 53 45 27	CsI 59 53 45 34
	DQE 0.5 lp/mm 1 lp/mm 2 lp/mm 3 lp/mm	-	Gadox 37 31 20 9	Gadox 37 31 20 11
	MTF 0.5 lp/mm 1 lp/mm 2 lp/mm 3 lp/mm	-	CsI 81 58 28 15	CsI 87 71 43 22

	MTF 0.5 lp/mm 1 lp/mm 2 lp/mm 3 lp/mm	-	Gadox 80 56 24 10	Gadox 80 56 26 11
	Resolution	-	3.5 lp/mm	4.0 lp/mm
Communication Method		Wireless	Wired	Wired, Wireless

9. Summary of Non-Clinical Data

A comparison test was conducted between the subject devices (FXRD-1012NA, FXRD-1012NB, FXRD-1012NAW and FXRD-1012NBW) and the predicate device (K122866) on the items such as DQE, MTF and spatial resolution.Test results support that the subject device is substantially equivalent to the predicate device.

These detectors comply with the following international and FDA-recognized consensus standards:

[IEC 60601-1 2005, Edition 3.0]	Medical Electrical Equipment -- Part 1: General Requirements For Basic Safety And Essential Performance
[IEC 60601-1-2, Edition 3]	Medical Electrical Equipment - Part 1-2: General Requirements For Basic Safety And Essential Performance - Collateral Standard: Electromagnetic Compatibility - Requirements And Tests
[IEC 62220-1, Edition 1.0]	Medical electrical equipment - Characteristics of digital X-ray imaging devices - Part 1: Determination of the detective quantum efficiency
[NEMA PS 3.1 - 3.20 2011]	Digital Imaging and Communications in Medicine (DICOM) Set
[ETSI] [EN 300 328 1.8.1]	Electromagnetic compatibility and Radio spectrum Matters (ERM); Wideband transmission systems; Data transmission equipment operating in the 2,4 GHz ISM band and using wide band modulation techniques; Harmonized EN covering the essential requirements of article 3.2 of the R&TTE Directive
[ETSI EN 301 893 1.7.1]	Broadband Radio Access Networks (BRAN); 5 GHz high performance RLAN; Harmonized EN covering the essential requirements of article 3.2 of the R&TTE Directive
[IEC 62133, Edition 2.0]	IEC 62133 Edition 2.0 2012-12 Secondary Cells And Batteries Containing Alkaline Or Other Non-Acid Electrolytes•Safety Requirements For Portable Sealed Secondary Cells, And For Batteries Made From Them, For Use In Portable Applications [Including: Corrigendum 1 (2013)

10. Summary of Clinical Data

A single-blinded concurrence study according to CDRH's Guidance for the Submission of 510(k)'s for Solid State X-ray Imaging Devices was conducted, and the study confirmed that the new x-ray detectors FXRD-1012NA, FXRD-1012NB, FXRD-1012NAW and FXRD-1012NBW provide images of equivalent diagnostic capability to the predicate device(K122865), the ViVIX-S wireless (FXRD-1417WA and FXRD-1417WB), and its results demonstrate substantial equivalence.

11. Conclusion [21 CFR 807.92(b) (3)]

The FXRD-1012NA, FXRD-1012NB, FXRD-1012NAW and FXRD-1012NBW Digital X-ray detectors are substantially equivalent to the currently marketed and predicate devices (K122865, and K122866) in terms of design features, fundamental scientific technology, indications for use, and safety and effectiveness.

Additionally, Substantial equivalence was demonstrated through the non-clinical performance, which complied with the requirements specified in the international and FDA-recognized consensus standards, IEC60601-1, IEC 60601-1-2, IEC62220-1 and NEMA PS 3.1 - 3.20, IEC 62133 and the clinical test, which complied with the requirements specified in the CDRH's Guidance for the Submission of 510(k)'s for Solid State X-ray Imaging Devices.

The results of these tests demonstrate that FXRD-1012NA, FXRD-1012NB, FXRD-1012NAW and FXRD-1012NBW Digital X-ray detectors meet the acceptance criteria and are adequate for this intended use. The comparison of technological characteristics, non-clinical performance data, safety testing, and clinical image concurrence data demonstrates that the device is as safe, as effective, and performs as well the predicate devices.