DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

February 8, 2017

Vieworks Co., Ltd.
% Ms. Priscilla Chung
Regulatory Affairs Consultant
LK Consulting Group USA, Inc.
800 Roosevelt Suite 417
IRVINE CA 92620

Re: K163703
Trade/Device Name: VIVIX-S 1417N
Regulation Number: 21 CFR 892.1680
Regulation Name: Stationary x-ray system
Regulatory Class: II
Product Code: MQB
Dated: January 5, 2017
Received: January 9, 2017

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,

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)*

K163703

Device Name
VIVIX-S 1417N

Indications for Use *(Describe)*

VIVIX-S 1417N Series is used for the general-purpose diagnostic procedures, and as well as intended to replace radiographic film / screen systems. The VIVIX-S 1417N Series is not intended for mammography applications.

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)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510(k) Summary

[As required by 21 CFR 807.92]

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

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

02/06/2017

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:	Kim, Jordin / Regulatory AffairsAssociate
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 1417N
Model Name:	FXRD-1417NAW FXRD-1417NBW
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)]

510(k) Number:	**K152894**
Product Code:	MQB
Classification Name:	Stationary x-ray system
Classification Regulation:	21 CFR 892.1680
Applicant:	Vieworks Co., Ltd.
Trade Name:	VIVIX-S 1717N
Model Name:	FXRD-1717NA FXRD-1717NB FXRD-1717NAW FXRD-1717NBW
Decision Date:	02/26/2016
Type:	Traditional

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

- General Description

Models FXRD-1417NAW and FXRD-1417NBW 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, andimage information sharing on the network.

- Differences between models

Models FXRD-1417NAW and FXRD-1417NBW are digital X-ray flat panel detectors, and each model has a 14 x 17 inch imaging area.
Both FXRD-1417NAW and FXRD-1417NBW communicate by using a wireless communication feature (IEEE 602.lla/b/g/n).
The scintillator used in FXRD-1417NAW is CsI andGadox was used for FXRD-1417NBW.

- Device Integration21 CFR 1020.30 (a) (1)(ii)

Mode	Description
AED	The detector detects X-ray exposure from the generator automatically and then performs image acquisition without any cable connection.
DR Trigger	The detector and generator receive and send their signal to each other for image acquisition. SCU and X-ray generator should be connected with the generator interface cable.

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

FXRD-1417NAW and FXRD-1417NBW 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.

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

Comparisons with the predicate, devices show the technological characteristics of the proposed FXRD-1417NAW and FXRD-1417NBW 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 (K152894), the FXRD-1417NAW and FXRD-1417NBW presented in this submission has the same:

- Intended Use
- Operating principle
- Design features
- Communication Method
- Scintillator Materials
- Resolution

There is similar performance as follow.

- Performance (MTF)
- Performance (DQE)

There are no significant difference between the FXRD-1717NAW and FXRD-1717NBW and the predicate device 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	Predicate Devices	Subject Device
510(k) Number	K152894	K163703
Manufacturer	Vieworks Co., Ltd.	
Model Name	FXRD-1717NA, FXRD-1717NB, FXRD-1717NAW, FXRD-1717NBW	FXRD-1417NAW, FXRD-1417NBW
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		FXRD-1717NA, FXRD-1717NB, FXRD-1717NAW and FXRD-1717NBW 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.	FXRD-1417NAW and FXRD-1417NBW 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
	Field of View	17 x 17inch	14 x 17inch
	Dimensions (H x W x D)	460.0 x 460.0 x 15.5mm	384mm x 460mm x 15.0mm
	Pixel Pitch	0.14mm	0.14mm
Materials Scintillator		CsI: TI, Gd2O2S:Tb	CsI: TI, Gd2O2S:Tb
DataTransmission	Wired	Max. 1Gbps	Max. 1Gbps
	Wireless	• IEEE802.11n: Max. 300Mbps (MIMO 2X2)	• IEEE802.11n: Max. 450Mbps (MIMO 3X3) • IEEE802.11ac: Max. 1300Mbps (MIMO 3X3)
Communication Method		Wired only Wireless & Wired	Wireless & Wired
Performance	DQE	FXRD-1717NAW: min. 47 (typ.50)	FXRD-1417NAW: min. 47 (typ.50)
		FXRD-1717NBW: min. 25 typ.(27)	FXRD-1417NBW: min. 25 typ.(27)
	MTF	FXRD-1717NAW: min. 68 (typ. 72)	FXRD-1417NAW: min. 68 (typ. 72)
		FXRD-1717NBW: min. 58 (typ. 60)	FXRD-1417NBW: min. 58 (typ. 60)
	Resolution	3.5 lp/mm	3.5 lp/mm
	Sensitivity linearity	FXRD-1717NAW: Linear	FXRD-1417NAW: Linear
		FXRD-1717NBW: Linear	FXRD-1417NBW: Linear
	NPS	FXRD-1717NAW: 0.9	FXRD-1417NAW: 0.9
		FXRD-1717NBW:	FXRD-1417NBW:

		1.09	1.09
	Spatial Resolution	FXRD-1717NAW: 4.1-4.3	FXRD-1417NAW: 4.1-4.3
		FXRD-1717NBW: 3.8-4.1	FXRD-1417NBW: 3.8-4.1
	Minimum Dose	FXRD-1717NAW: 0.2 uGy (2.5-2.8 cycles/mm)	FXRD-1417NAW: 0.2 uGy (2.5-2.8 cycles/mm)
		FXRD-1717NBW: 0.3 uGy(2.5-2.8 cycles/mm)	FXRD-1417NBW: 0.3 uGy(2.5-2.8 cycles/mm)
	Lag	FXRD-1717NAW: Non	FXRD-1417NAW: Non
		FXRD-1717NBW: Non	FXRD-1417NBW: Non
	Quantum Limited Performance	FXRD-1717NAW: 0.004 (mR)	FXRD-1417NAW: 0.004 (mR)
		FXRD-1717NBW: 0.008(mR)	FXRD-1417NBW: 0.008(mR)
	Image Acquisition	2.0-2.5 sec	2.0-2.5 sec
	Black Level	800-1,600	800-1,600

9. Summary of Non-Clinical Data

A comparison test was conducted between the subject devices (FXRD-1417NAW and FXRD-1417NBW) and the predicate device (K152894) on the items such as DQE, MTF and spatial resolution.

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

[IEC 60601-1 2005, Edition 3.1]	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
[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)

Test Item	Type	Subject Device	Predicate Device
Sensitivity linearity	CsI	Linear	Linear
	Gadox	Linear	Linear
MTF	CsI	min. 68 (typ. 72)	min. 68 (typ. 72)
	Gadox	min. 58 (typ. 60)	min. 58 (typ. 60)
DQE	CsI	min. 47 (typ.50)	min. 47 (typ.50)
	Gadox	min. 25 typ.(27)	min. 25 typ.(27)
NPS	CsI	0.9	0.96
	Gadox	1.09	1.165
Spatial Resolution	CsI	4.1-4.3	4.3-4.5
	Gadox	3.8-4.1	4.3-4.5
Minimum Dose	CsI	0.2 uGy (2.5-2.8 cycles/mm)	0.2 uGy (2.5-2.8 cycles/mm)
	Gadox	0.3 uGy(2.5-2.8 cycles/mm)	0.3 uGy(2.5-2.8 cycles/mm)
Lag	CsI	None	None
	Gadox	None	None

Quantum Limited Performance	CsI	0.004 (mR)	0.008 (mR)
	Gadox	0.008(mR)	0.014 (mR)
Image Acquisition	-	2.0-2.5 sec	2.0-2.5 sec
Black Level	-	800-1,600	1,400-1,500

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-1417NAW and FXRD-1417NBW provide images of equivalent diagnostic capability to the predicate devices, the VIVIX-S 1717N, and its results demonstrate substantial equivalence.

Clinical images were provided; these images were not necessary to establish substantial equivalence based on the differences from the predicate but they provide further evidence in addition to the laboratory performance data to show that the complete system works as intended.

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

The FXRD-1417NAW and FXRD-1417NBW Digital X-ray detectors are substantially equivalent to the currently marketed and predicate devices(K152894) 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-1417NAW and FXRD-1417NBW 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.