July 20, 2022

Vieworks Co., Ltd.
% Ms. Priscilla Chung
Regulatory Affairs Consultant
LK Consulting Group USA, Inc.
18881 Von Karman Avenue, Suite 160
IRVINE CA 92612

Re: K221512
Trade/Device Name: VIVIX-S FW (Model: FXRD-4343FAW, FXRD-3643FAW, FXRD-2530FAW)
Regulation Number: 21 CFR 892.1680
Regulation Name: Stationary x-ray system
Regulatory Class: Class II
Product Code: MQB
Dated: May 24, 2022
Received: May 27, 2022

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Laurel Burk, Ph.D.
Assistant Director
Diagnostic X-Ray Systems Team
DHT8B: Division of Radiological Imaging Devices and Electronic Products
OHT8: Office of Radiological Health
Office of Product Evaluation and Quality
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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K221512

Device Name
VIVIX-S FW (Model: FXRD-4343FAW, FXRD-3643FAW, FXRD-2530FAW)

Indications for Use *(Describe)*
VIVIX-S FW series is used for the general-purpose diagnostic procedures, and as well as intended to replace radiographic film/ screen systems. The VIVIX-S FW 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

(K221512)

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

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

6/30/2022

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, 14055 Republic of Korea
Contact Name:	Oh, Kevin / Regulatory Affairs Associate
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 FW
Model Name:	FXRD-4343FAW, FXRD-3643FAW, FXRD-2530FAW
Common Name:	Digital Flat Panel X-ray Detector
Classification Name:	Regulation 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:	**K200418**
Applicant:	Vieworks Co., Ltd.
Trade Name:	VIVIX-S 4343VW PLUS
Model Name:	FXRD-4343VAW PLUS
Common Name:	Digital Flat Panel X-ray Detector
Classification Name:	Regulation Name: Stationary X-Ray System
Classification Panel:	Radiology
Classification Regulation:	21 CFR 892.1680
Product Code:	MQB
Device Class:	2
Decision Date:	03/18/2020
Type:	Traditional

510(k) Number:	**K200418**
Applicant:	Vieworks Co., Ltd.
Trade Name:	VIVIX-S 3643VW PLUS
Model Name:	FXRD-3643VAW PLUS
Common Name:	Digital Flat Panel X-ray Detector
Classification Name:	Regulation Name: Stationary X-Ray System
Classification Panel:	Radiology
Classification Regulation:	21 CFR 892.1680
Product Code:	MQB
Device Class:	2
Decision Date:	03/18/2020
Type:	Traditional

510(k) Number:	**K200418**
Applicant:	Vieworks Co., Ltd.
Trade Name:	VIVIX-S 2530VW PLUS
Model Name:	FXRD-2530VAW PLUS
Common Name:	Digital Flat Panel X-ray Detector
Classification Name:	Regulation Name: Stationary X-Ray System
Classification Panel:	Radiology
Classification Regulation:	21 CFR 892.1680
Product Code:	MQB
Device Class:	2
Decision Date:	03/18/2020
Type:	Traditional

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

- General Description

VIVIX-S -FW, a series for of flat panel detectors models named; FXRD-2530FAW, FXRD-3643FAW, FXRD-4343FAW, with imaging areas of 25cm x 30cm, 36cm x 43cm, 43cm x 43cm, respectively. The detectors can acquire static images as well as fluoroscopic images up to 6fps.

The device intercepts x-ray photons and the scintillator (Cesium Iodide) emits visible spectrum photons that illuminate an array of photo (a-SI)-detectors that create electrical signals. After the electrical signals are generated, it is converted to digital value. This digital value is transmitted either by wire via cable or wirelessly through a system control unit (SCU), and the software called Vxvue acquires and processes the data values from the detector. The SW is of moderate level of concern. On the Vxvue, the use can view as well as perform basic manipulations such as (rotation, enlargement, etc.) on the acquired images. These devices should be integrated with an operating PC and an X-Ray generator. It can be utilized to digitalize x-ray images and transfer for radiography diagnostic.

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

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

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

Comparisons with the predicate, devices show the technological characteristics of the proposed VIVIX-S FW device to be substantially equivalent to the predicate devices. The proposed devices are functionally similar to the predicate devices.

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

When compared to the predicate devices (**K200418**), the VIVIX-S FW presented in this submission has the same:

- Intended Use
- Technological characteristics
- 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 VIVIX-S FW 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 Device	Subject Device	Equivalence
510(k) Number	K200418	-	-
Manufacturer	Vieworks Co., Ltd.		-
Device Name	VIVIX-S 4343VW	VIVIX-S 4343FW	-
Detector	VIVIX-S 4343VAW PLUS	FXRD-4343FAW	-
SCU	FXRS-04A FXRP-02A	FXRS-04A FXRP-03A	**Power Supply**
Software	VXvue	VXvue	**Software**
Common Name	Digital Flat Panel X-ray Detector		**Equivalent**
Classification Name	Solid State X-Ray Imager (Flat Panel/Digital Imager)		**Equivalent**
Classification Panel	Radiology		**Equivalent**

Classification Regulation	21 CFR 892.1680		**Equivalent**
Product Code	MQB		**Equivalent**
Device Class	2		**Equivalent**
Indications for Use	The VIVIX-S VW detectors are used for the general-purpose diagnostic procedures, and as well as intended to replace radiographic film / screen systems. The VIVIX-S VW detectors are not intended for mammography applications.	The VIVIX-S FW detectors are used for the general-purpose diagnostic procedures, and as well as intended to replace radiographic film / screen systems. The VIVIX-S VW detectors are not intended for mammography applications.	**Equivalent**
MTF (Measured Values, at 1lp/mm)	FXRD-4343VAW PLUS: 60	FXRD-4343FAW: 76	
DQE (Measured Values, at 1lp/mm)	FXRD-4343VAW PLUS: 53	FXRD-4343FAW: 45	
Spatial Resolution	3.5 lp/mm	5 lp/mm	

Parameter	**Predicate Device**	**Subject Device**	**Equivalence**
510(k) Number	K200418	-	-
Manufacturer	Vieworks Co., Ltd.		-
Device Name	VIVIX-S 3643VW PLUS	VIVIX-S 3643FW	-
Detector	FXRD-3643VAW PLUS	FXRD-3643FAW	-
SCU	FXRS-04A FXRP-02A	FXRS-04A FXRP-03A	Power Supply
Software	VXvue	VXvue	Software
Common Name	Digital Flat Panel X-ray Detector		Equivalent
Classification Name	Solid State X-Ray Imager (Flat Panel/Digital Imager)		Equivalent
Classification Panel	Radiology		Equivalent
Classification Regulation	21 CFR 892.1680		Equivalent
Product Code	MQB		Equivalent
Device Class	2		Equivalent
Indications for Use	The VIVIX-S VW detectors are used for the general-purpose diagnostic procedures, and as well as intended to replace radiographic film / screen systems. The VIVIX-S VW detectors are not intended for	The VIVIX-S FW detectors are used for the general-purpose diagnostic procedures, and as well as intended to replace radiographic film / screen systems. The VIVIX-S VW detectors are not intended for	Equivalent

	mammography applications.	mammography applications.	
MTF (Measured Values, at 1lp/mm)	FXRD-3643VAW PLUS: 59	FXRD-3643FAW: 74	
DQE (Measured Values, at 1lp/mm)	FXRD-3643VAW PLUS: 51	FXRD-3643FAW: 41.5	
Spatial Resolution	3.5lp/mm	5lp/mm	

Parameter		Predicate Device	Subject Device	Equivalence
510(k) Number		K200418	-	-
Manufacturer		Vieworks Co., Ltd.		-
Device Name		VIVIX-S 2530VW PLUS	VIVIX-S 2530FW	-
	Detector	FXRD-2530VAW PLUS	FXRD-2530FAW	-
	SCU	FXRS-04A FXRP-02A	FXRS-04A FXRP-03A	Power Supply
	Software	VXvue	VXvue	Software
Common Name		Digital Flat Panel X-ray Detector		Equivalent
Classification Name		Solid State X-Ray Imager (Flat Panel/Digital Imager)		Equivalent
Classification Panel		Radiology		Equivalent
Classification Regulation		21 CFR 892.1680		Equivalent
Product Code		MQB		Equivalent
Device Class		2		Equivalent
Indications for Use		The VIVIX-S VW detectors are used for the general-purpose diagnostic procedures, and as well as intended to replace radiographic film / screen systems. The VIVIX-S VW detectors are not intended for mammography applications.	The VIVIX-S FW detectors are used for the general-purpose diagnostic procedures, and as well as intended to replace radiographic film / screen systems. The VIVIX-S VW detectors are not intended for mammography applications.	Equivalent
MTF (Measured Values, at 1lp/mm)		FXRD-2530VAW PLUS: 60	FXRD-2530FAW: 76	
DQE (Measured Values, at 1lp/mm)		FXRD-2530VAW PLUS: 52	FXRD-2530FAW: 46	
Spatial Resolution		4.0 lp/mm	4.0 lp/mm	

9. Summary of Non-Clinical Data

A comparison test was conducted between the subject devices (VIVIX-S VW) and the predicate device on the items such as DQE, MTF and spatial resolution.

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

- 21CFR1020.30, Diagnostic X-ray Systems and their major components
- 21CFR1020.31, Radiographic equipment
- - IEC 60601-1 Medical Electrical Equipment -- Part 1: General Requirements for Basic Safety and Essential Performance.
- CAN/CSA-C22.2 No. 60601-1 (2008) (Medical Equipment –Part 1 : General Requirements for Basic Safety and Essential Performance) (includes National Differences for Canada)
- ANSI/AAMI ES60601-1 (2005+ C1:09+A2:10) (Medical Electrical Equipment – Part 1
- IEC 60601-1-2 Medical Electrical Equipment - Part 1-2 : General Requirements for Basic Safety and Essential Performance - Collateral Standard: Electromagnetic Compatibility - Requirements and Tests

Test results are all a pass, and they indicate device safety and effectiveness.

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 VIVIX-S FW provide images of equivalent diagnostic capability to the predicate devices, the VIVIX-S 4343VW, VIVIX-S 3643VW, VIVIX-S 2530VW and its results demonstrate substantial equivalence.

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

The VIVIX-S FW Digital X-ray detectors are substantially equivalent to the currently marketed and predicate devices (K200418) 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, 3 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 VIVIX-S FW Digital X-ray detectors meets the acceptance criteria and is 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.