September 13, 2022

Vieworks Co., Ltd.
℅ Priscilla Chung
Regulatory Affairs Consultant
LK Consulting Group USA, Inc.
18881 Von Karman Ave., STE 160
IRVINE CA 92612

Re: K220239
Trade/Device Name: VIVIX-S 4386W
Regulation Number: 21 CFR 892.1680
Regulation Name: Stationary X-Ray System
Regulatory Class: Class II
Product Code: MQB
Dated: August 10, 2022
Received: August 12, 2022

Dear Priscilla 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)*
K220239

Device Name
VIVIX-S 4386W

Indications for Use *(Describe)*
VIVIX-S 4386W 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. It is intended for both adult and pediatric populations.

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 (K220239)

[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)]

09/06/2022

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

Name of Sponsor:	Vieworks Co., Ltd.
Address:	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 4386W
Model Name:	FXRD-4386WB
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

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

510(k) Number:	K181003
Product Code:	MQB
Applicant:	Vieworks Co., Ltd.
Trade Name:	VIVIX-S 1717V
Decision Date:	03/15/2018
Type:	Traditional

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

General Description
VIVIX-S 4386W, a flat panel detector model named; FXRD-4386WB with imaging areas of 43cm x 86cm. The device intercepts x-ray photons and the scintillator 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, and the Software which acquires and processes the data values from the detector. The resulting digital images will be displayed on monitors. 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 4386W 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. It is intended for both adult and pediatric populations.

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

Comparisons with the predicate, the system shows the technological characteristics of the proposed device 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 (K181003), the VIVIX-S 4386W presented in this submission has the subsequently equivalent:

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

The MTF value of the subject device is higher than the one of the predicate device models (FXRD-1717VB) but DQE value of is little lower than the predicate device. However, the difference is not significant (just one 1lp/mm value difference), and the test result of the concurrence clinical study shows that this difference does not raise an issue in substantial equivalence.

Based on the information and the test result we submitted, we conclude that the subject device is substantially equivalent to these devices in design, function, materials, operational principles and intended use.

Table 1: Comparison of Subject Device VIVIVX-S 4386W to the Predicate

Parameter		Predicate Device	Subject Device	Equivalence
510(k) Number		K181003	K220239	-
Manufacturer		Vieworks Co., Ltd.		-
Device Name		VIVIX-S 1717V	VIVIX-S 4386W	-
Compo-nent	Detector	FXRD-1717VA, FXRD-1717VB	FXRD-4386WB	-
	SCU	-	FXRS-04A	Power Supply
	Software	VXvue	VXvue	Equivalent

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		VIVIX-S 1717V series 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 4386W 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. It is intended for both adult and pediatric populations.	Equivalent
Design	Panel Shape	Square Panel	Square Panel	Equivalent
	Field of View	17 x 17inch	17 x 34inch	Similar
	Dimensions (H x W x D)	460.0 x 460.0 x 15.5mm	900 ㎜ × 465 ㎜ × 17.0 ㎜	Equivalent
	Pixel Pitch	0.14mm	0.14mm	Equivalent
	Weight	4.5kg	8kg (With two battery packs)	
Materials Scintillator		Csl: TI, Gd2O2S:Tb	Gd2O2S:Tb:	Substantially Equivalent
Image sensor		TFT: a-Si (Amorphous Silicon)	TFT: a-Si (Amorphous Silicon)	Equivalent
Data Transmis-sion	Wired	Max. 1Gbps	Max. 1Gbps	Equivalent
Communication Method		Wired	Wired / Wireless	Substantially Equivalent
Perform-ance	MTF (1lp/mm)	FXRD-1717VA: Horizontal 66 Vertical 67 FXRD-1717VB: Horizontal 58 Vertical 58	FXRD-4386W: 62	Substantially Equivalent
	DQE (1lp/mm)	FXRD-1717VA: Horizontal 53 Vertical 54	FXRD-4386W: 28	Substantially Equivalent

		FXRD-1717VB: Horizontal 29 Vertical 29		
	Resolution	3.5 lp/mm	3.5 lp/mm	Equivalent
Active Area		430.08 x 430.08 (mm)	430.08 ㎜ × 860.16 ㎜ 430.08 ㎜ × 430.08 ㎜	Substantially Equivalent
Pixel Size		140 ㎛	140 ㎛	Equivalent
Grayscale		16 bit	16 bit	Equivalent
Image Acquisition Time	Wired	1.5 sec	Max. 5 sec. (Exposure time is set to 500ms, Excluding exposure time)	Similar
	Wireless		• Max. 5 sec. (IEEE802.11ac, MiMO 3x3, 5GHz, 80MHz) (Exposure time is set to 500ms, Excluding exposure time)	
Active Array		3072 x 3072 pixels	3072 x 6144 pixels 3072 x 3072 pixels	Substantially Equivalent
Method of Generator Interface		• DR Trigger (External Line Trigger) • AED (Auto Exposure Detection) • Passive Trigger (External Line Trigger)	• DR Trigger (External Line Trigger) • AED (Auto Exposure Detection) • Software Trigger	Substantially Equivalent
Spatial Resolution		3.5lp/mm	Min. 3.5lp/mm	Equivalent
Technology		Structured scintillator is attached in the detector to increase the X-ray photon interaction, X-ray absorption, and the amount of available visible light. This enhances potential detective quantum efficiency and partial resolution.	Structured scintillator is attached in the detector to increase the X-ray photon interaction, X-ray absorption, and the amount of available visible light. This enhances potential detective quantum efficiency and partial resolution.	Equivalent
Principle of Operation		Generated X-ray photons strike the scintillator causing the visible light emission that is to be converted into an electric charge by the photodiode array. The electric	Generated X-ray photons strike the scintillator causing the visible light emission that is to be converted into an electric charge by the photodiode array. The electric	Equivalent

	charge is then collected at each photodiode and turns into a digital value by using the underlying readout electronics.	charge is then collected at each photodiode and turns into a digital value by using the underlying readout electronics.	

9. Summary of Non-Clinical Data

A comparison test was conducted between the subject devices (VIVIX-S 4386W) and the predicate device (K181003) 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

10. Summary of Clinical Data

A single-blinded concurrence study was conducted, and the study confirmed that the new VIVIX-S 4386W provides images of equivalent diagnostic capability to the predicate devices, the VIVIX-S 1717V and its results demonstrate substantial equivalence.

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

The VIVIX-S 4386W is substantially equivalent to the currently marketed and predicate devices (K181003) 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.
The results of these tests demonstrate that VIVIX-S 4386W 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.