510(k) Summary

[As required by 21 CFR 807.92]

K190611

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

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

03/28/2019

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 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 1751S
Model Name:	VIVIX-S 1751S
Common Name:	Digital Flat Panel X-ray Detector
Regulation Name:	Stationary X-Ray System
Classification Panel:	Radiology
Regulation Number:	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**
Applicant:	Vieworks Co., Ltd.
Decision Date:	03/15/2018
Type:	Traditional
Trade Name:	VIVIX-S 1717V
Model Name:	FXRD-1717VA FXRD-1717VB
Common Name:	Digital Flat Panel X-ray Detector
Regulation Name:	Stationary X-Ray System
Classification Panel:	Radiology
Regulation Number:	21 CFR 892.1680
Product Code:	MQB
Device Class:	2

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

- General Description

VIVIX-S 1751S, whose model name is VIVIX-S 1751S with 17X51 inches of imaging area. The device intercepts x-ray photons, and its Gadox (Gadolinium Oxysulfide) 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 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. The detector can communicate with the generator by cable. It is utilized for capturing and transfer of digital x-ray images for radiography diagnosis. The X-ray generator and the imaging software are not part of the VIVIX-S 1751S.

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

VIVIX-S 1751S series is used for the general-purpose diagnostic procedures, and as well as intended to replace radiographic film/ screen systems. The VIVIX-S 1751S 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 1751S 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 (K**181003**), the VIVIX-S 1751S 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)

For the predicate device, VIVIX-S 1717V, only one panel (for 17x17 inch imaging) is used. For this type of detector to capture images for longer body parts such as whole spine or legs, an imaging process (stitching) on the 3 separately taken images from 3 exposures are required to create one long image.

On the other hand, the VIVIX-S 1751S detector features 3 of the panels to create longer images (17 x 34 inches and 17x51 inches) for single exposure and without the stitching process. 17 x 17 size image can be also captured with this type of detector as well.

Parameter		Predicate Device	Subject Device	Equivalence
510(k) Number		K181003	-	-
Manufacturer		Vieworks Co., Ltd.		-
Device Name		VIVIX-S 1717V	VIVIX-S 1751S	-
	Detector	FXRD-1717VA, FXRD-1717VB	FXRD-1751SB	-
	Power Supply Unit	-	FXRP-01A	Power Supply
	IO Box	FXRI-01A	-	Power Supply
	Software	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
Intended 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 1751S series is used for the general-purpose diagnostic procedures, and as well as intended to replace radiographic film/ screen systems. The VIVIX-S 1751S series is not intended for mammography applications.	Equivalent

Parameter		Predicate Device	Subject Device	Equivalence
Device Name		VIVIX-S 1717V	VIVIX-S 1751S	-
Design	Panel Shape	Square Panel	Square Panel	Equivalent
	Field of View	17 x 17inch	17 x 51inch	3 times longer*
	Dimensions (H x W x D)	460.0 x 460.0 x 15.5mm	1357.0 x 532.0 x 30.0mm	Equivalent
	Pixel Pitch	0.14mm	0.14mm	Equivalent
	Weight	4.5kg	About 4.5kg	Equivalent
Materials Scintillator		CsI: Tl, Gd2O2S:Tb	Gd2O2S:Tb	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	Equivalent
Performa-nce	DQE (1lp/mm)	FXRD-1717VA: 40~60 (typ. 48%)	CsI Type Not Available	Equivalent
		FXRD-1717VB: 20~40 (typ. 27%)	FXRD-1751SB: 20%	
	MTF (1lp/mm)	FXRD-1717VA: 50~70 (typ. 70%)	CsI Type Not Available	Equivalent
		FXRD-1717VB: 40~60 (typ. 58%)	FXRD-1751SB: 40%	
	Resolution	3.5 lp/mm	3.5 lp/mm	Equivalent
Active Area		430.08 x 430.08 (mm)	430.08(mm) x 430.08(mm) 430.08(mm) x 860.16(mm) 430.08(mm) x 1290.24(mm)	The candidate device features 3 of the panels used for the predicate device.
Pixel Size		140 ㎛	140 ㎛	Equivalent
Grayscale		16 bit	16 bit	Equivalent
Image Acquisition Time		1.5 sec. (wired)	10 sec.	Longer
Active Array		3072 x 3072 pixels	3072 x 3072 pixels 3072 x 6144 pixels 3072 x 9216 pixels	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)	Equivalent
Spatial Resolution		3.5lp/mm	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	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	Equivalent

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

9. Summary of Non-Clinical Data

A comparison test was conducted between the subject devices (VIVIX-S 1751S) 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
- FDA guidance titled “Content of Premarket Submissions for Management of Cybersecurity in Medical Devices”

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 1751S provide 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 1751S Digital X-ray detectors are 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, 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 1751S 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.