Rayence Co., Ltd.
℅ Mr. Dave Kim
Medical Device Regulatory Affairs
Mtech Group
7505 Fannin St., Suite 610
HOUSTON TX 77054

April 28, 2021

Re: K210985
Trade/Device Name: 1717FCC
Regulation Number: 21 CFR 892.1680
Regulation Name: Stationary x-ray system
Regulatory Class: Class II
Product Code: MQB, JAA
Dated: March 26, 2021
Received: April 1, 2021

Dear Mr. Kim:

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,

For

Thalia T. Mills, Ph.D.
Director
Division of Radiological Health
OHT7: Office of In Vitro Diagnostics
and 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)*
K210985

Device Name
1717FCC

Indications for Use *(Describe)*

1717FCC 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.

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
K210985

This summary of 510(k) safety and effectiveness information is being submitted in accordance with requirements of 21 CFR Part 807.92.

Date 510k summary prepared: April 16, 2021

Submitter's Name, address, telephone number, a contact person:

Submitter's Name : Rayence Co., Ltd.
Submitter's Address: 14, Samsung 1-ro 1-gil, Hwaseong-si, Gyeonggi-do, Korea
Submitter's Telephone: +82-31-8015-6459
Contact person: Mr. Kee Dock Kim / RA Team Manager / +82-31-8015-6459
Official Correspondent: Dave Kim **(**davekim@mtech-inc.net**)**
Address: 7505 Fannin St. Ste 610-V111, Houston, TX 77054
Telephone: +713-467-2607

Name of the device, including the trade or proprietary name if applicable, the common or usual name and the classification name, if known:

Trade/proprietary name **:** 1717FCC
Common Name : Digital Flat Panel X-ray Detector
Regulation Number : 21 CFR 892.1680
Regulation Name : Stationary X-ray System
Regulatory Class : Class II
Product Code : MQB, JAA

Primary Predicate Device :
Trade/Device Name : 1717SCC_127μm and 1717SCC_140μm
Common Name : Digital Flat Panel X-ray Detector
510(k) Number : K171420
Regulation Number : 21 CFR 892.1680
Regulation Name : Stationary X-ray System
Regulatory Class : Class II

Product Code	: MQB

Reference Device:

Trade/Device Name	: DRF 4343 (Pixium RF 4343)
510(k) Number	: K080859
Regulation Number	: 21 CFR 892.1650
Regulation Name	: Image intensified Fluoroscopic X-ray system
Regulatory Class	: Class II
Product Code	: JAA and MQB

2. Device Description

1717FCC is a digital solid state X-ray detector that is based on flat-panel technology. This radiographic image detector and processing unit consists of a scintillator coupled to amorphous silicon (a-Si) / Indium Gallium Zinc Oxide (IGZO) on TFT sensor. This device is connected to the user PC via wired LAN (ethernet cable) and it needs to be integrated with a radiographic imaging system. It does not operate as an X-ray generator controller but can be utilized to capture and digitalize X-ray images for radiographic diagnosis. The RAW files can be further processed as DICOM compatible image files by separate console SW(Xmaru RF) for a radiographic diagnosis and analysis.

3. Indication for use

1717FCC 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.

4. Summary of Design Control Risk management

1717FCC digital X-ray detector is a modification of 1717SCC (K171420). 1717FCC was developed for the purpose of retrofitting the stationary X-ray system with a film detector.
The risks and the hazardous impact of the device modification were analyzed with FMEA method. The specific risk control and protective measures to mitigate the risks from the modification were reviewed and implemented in the new product design phase. The overall assessment concluded that all risks and hazardous conditions identified arising from the design change were successfully mitigated and accepted.

5. Summary of the technological characteristics of the device compared to the predicate device:

1717FCC detector described in this 510(k) has the same indications for use and similar technical characteristics as its predicate devices, 1717SCC (K171420).

5.1 Scintillator layer

**scintillator* layer. (* *scintillator : a phosphor that produces scintillations*)

Scintillator Type	Proposed	Predicate
CsI (Cesium Iodide)	1717FCC	1717SCC_127um and 1717SCC_140um

5.2 Power source

		Proposed 1717FCC	Predicate 1717SCC
Power	Type	Power adapter	Power supply
	Model name	AHM85PS24	RP003A
	Dimension	150 X 64 X 37 (cable length: 900 mm)	188 X 92 X 41.5
	Weight	0.4	0.5
	Rating	Input: 100-240 V, 1.0 A, 50/60 Hz Output: 24VDC (Max 3.54A)	Input: 100-240VAC (50/60Hz) Output: 24VDC (Max 1.7A)

5.3 Generator specifications

Model	Manufacture	Specification			
CMP 200	Communications & Power Industries		32kW	40kW	50kW
		kVp	40-125		40-150
		mA	10-400	10-500	10-630
EDITOR HFe 501	Rontgenwerk Bochum	kVp	40-150		
		mA	10-630		
UD150L-40E/40F	Shimadzu	kVp	40-150		
		mA	@100 kVp- 500(320)		
			@80 kVp- 630(400)		
PXR-321B	Poskom Co.,Ltd.	kVp	125/150		
		mA	500		

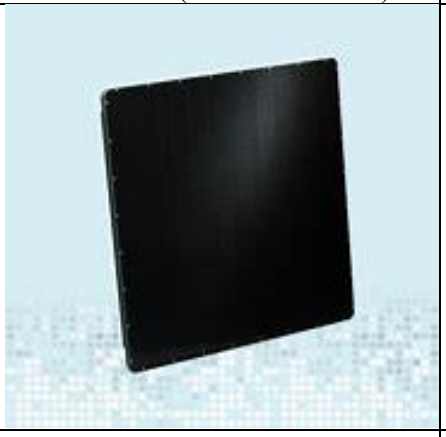
5.4 Comparison with the predicate device

Characteristic	Proposed Device (K210985)	Predicate Device (K171420)	

Manufacturer		**Rayence Co.,Ltd.**		**Rayence Co.,Ltd.**	
Product Name		1717FCC		1717SCC	
Feature					Similar
Indications for use		1717FCC 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.		1717SCC_127um and 1717SCC_140um, are 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.	Same
Detector Type		Amorphous Silicon (a-Si) TFT + PIN type photodiode IGZO TFT + PIN type photodiode (option)		Amorphous Silicon (a-Si) TFT	Similar
Scintillator		CsI:Tl	1717FCC	CsI:Tl	1717SCC	Similar
Imaging Area		17 x 17 inches		17 x 17 inches		Similar
Pixel matrix		140 type: 3000 x 3000 (Full resolution) 280 type: 1500 x 1500 (2x2 binning) 420 type: 1000 x 1000 (3x3 binning) 560 type: 750 x 750 (4x4 binning)		140 type : 3072 x 3072		Similar
Pixel pitch		140 µm / 280 µm/ 420 µm/ 560 µm		140 µm		Similar
A/D conversion		14 / 16 bit		14 bit / 16 bit		Same
MTF	a-Si TFT	1.0 lp/mm, Typ. 0.535		1.0 lp/mm, Typ. 0.580		Similar
		2.0 lp/mm, Typ. 0.220		2.0 lp/mm, Typ. 0.283		
		3.0 lp/mm, Typ. 0.099		3.0 lp/mm, Typ. 0.158		
		3.5 lp/mm, Typ. 0.073		3.5 lp/mm, Typ. 0.120		
	IGZO TFT	1.0 lp/mm, Typ. 0.525		-		
		2.0 lp/mm, Typ. 0.209				
		3.0 lp/mm, Typ. 0.092				
		3.5 lp/mm, Typ. 0.064				
DQE (0)	a-Si TFT	Typ. 0.751		0 lp/mm, Typ. 0.740		Similar
	IGZO TFT	Typ. 0.766		-		
Preview time		≤2 seconds		≤2 seconds		Same
Data output		RAW		RAW		Same

	*The RAW files are convertible into DICOM 3.0 by console S/W	*The RAW files are convertible into DICOM 3.0 by console S/W	
Dimensions	470 x 470 x 50 mm	460 × 460 × 15.5 mm	Similar
Weight	6.0 kg	4 kg (incl. battery)	Similar

5.5 Comparison with Reference Device

Manufacturer	**Rayence Co.,Ltd.**		**Villa Sistemi Medicali**	
Product Name	1717FCC		DRF 4343 (Pixium RF 4343)	
Feature				Similar
510(k) number	K210985		K080859	
Indications for use	1717FCC 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.		The DRF 4343 is intended to capture digital images from a radiographic / fluoroscopic system through a dynamic digital flat panel, to digitalize, archieve and review images and to provide a network connection via DICOM protocol to various output (e.t. hardcopy, softcopy and archive) devices which uses a device. This device is not intended for mamogrpahy use.	Similar
Detector Type	Amorphous Silicon (a-Si) TFT + PIN type photodiode IGZO TFT + PIN type photodiode		Amorphous Silicon (a-Si) TFT	Similar
Scintillator	CsI:Tl		CsI:Tl	Same
Imaging Area	17 x 17 inches		17 x 17 inches	Similar
Frame rate	GigE	6 @ (1x1) 25 @ (2x2) 45 @ (3x3) 60 @ (4x4)	8 f/s (RAD), 15 f/s for fluoroscopy 12 f/s (RAD), 18 f/s for fluoroscopy (large field)	Better
	Camera link	9 @ (1x1) 30 @ (2x2) 45 @ (3x3) 60 @ (4x4)		
	5GigE	15 @ (1x1)		

		30 @ (2x2) 45 @ (3x3) 60 @ (4x4)		
Image resoulution	Upto 3.5 lp/mm		Upto 3.4 lp/mm	Better

6. Summary of Performance Testing

1717FCC Digital Flat Panel X-Ray Detector has the same indications for use, the same scintillator material (CsI:Tl), the same generator specifications and the same risk analysis characteristics compared to 1717SCC, the predicate devices (K171420). The pixel matrix and pixel pitch sizes are different due to different imaging areas but the differences do not raise new concerns for the safety and effectiveness of the subject device.

The clinical and non-clinical test report for the subject device were prepared and submitted to FDA to demonstrate the substantial equivalency of the subject device performance compared to the predicate device.

After comparing a broad review of plain radiographic images taken with 1717FCC and 1717SCC_140μm, images obtained with 1717FCC and 1717SCC were equivalent quality for the same view obtained from a similar patient with the 1717SCC_140μm. In general, both the spatial and soft tissue contrast resolution are slightly superior using the 1717FCC. Specifically, the soft tissues on extremity films were seen with better clarity. There is little difficulty in evaluating a wide range of anatomic structures necessary to provide a correct conclusion.

The non-clinical test report contains the MTF, DQE and NPS performance test comparison between the subject device (1717FCC), and the predicate device (1717SCC), by using the identical test equipment and same analysis method described by IEC 62220-1.

The MTF and DQE testing represent the ability to visualize object details of a certain size and contrast. 1717FCC demonstrated equivalent or better performance in terms of MTF and DQE as well as NPS compared to 1717SCC, the predicate device, at all spatial frequencies.

The frame rate and image resolution for 1717 FCC, the subject device, perform better than the specification of the reference device, DRF 4343 (K080859) which are referenced in K131766.

Based on the non-clinical consideration evaluation, the sponsor can claim the substantial equivalency between the subject device and the predicate device in terms of diagnostic image quality.

The manufacturing facility is in conformance with the design control procedure requirements specified in 21 CFR 820.30 and the relevant 21CFR820 standards as the records are available for review. Furthermore, the device conforms with all labeling requirements as per 21 CFR Subchapter J, specifically, 21 CFR 10120.30 and 1020.32.

7. Summary for any testing and reference guidance:

- IEC 62220-1-1 Edition 1.0 2015-03 Medical electrical equipment-Characteristics of digital X-ray imaging devices Part 1-1: Determination of the detective quantum efficiencyDetectors used in radiographic imaging
- EMC testing were conducted in accordance with standard IEC 60601-1-2: 2014
- IEC 60601-1-6:2010 Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability
- Electrical, mechanical, environmental safety and performance testing according to standard IEC 60601-1: 2005, COR1:2006, COR2:2007, AMD1:2012 (Medical electrical equipment Part 1:General requirements for basic safety and essential performance) and IEC 60601-1-6:2010 (Third edition) +A1:2013
- Non-clinical consideration according to FDA Guidance "Guidance for the Submissions of 510(k)'s for Solid State X-ray Imaging Devices"
- "Guidance for the Contents of Premarket Submission for Software Contained in Medical Device".
- Pediatric Information for X-ray Imaging Device Premarket Notifications
- Content of Premarket Submissions for Management of Cybersecurity in Medical Devices

8. Conclusions:

In accordance with the performance outcomes, 1717FCC demonstrated equivalent or better performance compared to 1717SCC(K171420) and SkyPlate (K171461). Therefore, Rayence claims the substantial equivalency between the subject device and the predicate device in terms of diagnostic image quality about safety and effectiveness.