October 18, 2021

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

Re: K212753
Trade/Device Name: 0909FCB, 1212FCA
Regulation Number: 21 CFR 892.1680
Regulation Name: Stationary x-ray system
Regulatory Class: Class II
Product Code: MQB, JAA
Dated: October 12, 2021
Received: October 12, 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)*
K212753

Device Name
0909FCB, 1212FCA

Indications for Use *(Describe)*
Digital Flat Panel X-Ray Detector is indicated for digital imaging solution designed for human anatomy including head, neck, cervical spine, arm, leg and peripheral (foot, hand, wrist, fingers, etc.). It is intended to replace film based radiographic diagnostic systems and provide a case diagnosis and treatment planning for physicians and other health care professionals. 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
K212753

Date 510k summary prepared: October 6th,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	**:** 0909FCB, 1212FCA
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	:1212FCA
Common Name	: Digital Flat Panel X-ray Detector
510(k) Number	: K202722
Regulation Number	: 21 CFR 892.1680
Regulation Name	: Stationary X-ray System
Regulatory Class	: Class II
Product Code	: MQB

Reference Device :

Trade/Device Name	:1717FCC
Common Name	: Digital Flat Panel X-ray Detector
510(k) Number	: K210985
Regulation Number	: 21 CFR 892.1680
Regulation Name	: Stationary X-ray System
Regulatory Class	: Class II
Product Code	: MQB, JAA

2. Device Description

The 0909FCB flat panel detector employs a CsI:Tl scintillator for X-ray-to-light converter. Column-structurized CsI:Tl scintillator have high resolution performance due to much less light blurring, and is thus available for a longer period of time. CMOS active pixel detector makes extremely low noise level and highly sensitive performance. Due to seamless one chip CMOS, there is no data missing or artifacts. The high physical and functional performance of 0909FCB gives competitive image quality.
The RAW files can be further processed as DICOM compatible image files by separate console SW for a radiographic diagnosis and analysis.

The 1212FCA 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 an IGZO TFT sensor. This device needs to be integrated with a radiographic imaging system. It 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 for a radiographic diagnosis and analysis.
The subject detectors are connected to a viewing station by ethernet connection cable. There is no wireless option available.

The 0909 FCB and 1212FCA SSXI detectors should be tested and used with compatible X-ray generators which are not part of the imaging receptor device package.

3. Indication for use

Digital Flat Panel X-Ray Detector is indicated for digital imaging solution designed for human anatomy including head, neck, cervical spine, arm, leg and peripheral (foot, hand, wrist, fingers, etc.). It is intended

to replace film based radiographic diagnostic systems and provide a case diagnosis and treatment planning for physicians and other health care professionals. Not to be used for mammography.

4. Summary of Design Control Risk management

0909FCB digital X-ray detector is a modification of 1212FCA (K202722). 1212FCA is identical to 1212FCA (k202722). 0909FCB and 1212FCA were developed for the purpose of retrofitting the stationary X-ray system with a film detector. 0909FCB is slightly smaller than 1212FCA (K202722). 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:

0909FCB detector described in this 510(k) have the same indications for use and similar technical characteristics as its predicate devices, 1212FCA(K202722).

5.1 Scintillator layer

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

	Proposed	**Predicate**
CsI (Cesium Iodide)	0909FCB, 1212FCA	1212FCA

5.2. Power source

		Proposed 0909FCB	**Proposed** 1212FCA	**Predicate** 1212FCA
Power	Type	Power adapter	Power adapter	Power adapter
	Model name	AHM85PS12	AHM85PS24	AHM85PS24
	Dimension	135 X 62 X 37 (cable length: 900 mm)	150 X 64 X 37 (cable length: 900 mm)	150 X 64 X 37 (cable length: 900 mm)
	Weight	0.36kg	0.5kg	0.5kg
	Rating	Input: 100-240 Vac, 1.0 A, 50/60 Hz Output: 12VDC (7.08A)	Input: 100-240 Vac, 1.0 A, 50/60 Hz Output: 24VDC (Max 3.54A)	Input: 100-240 V, 1.0 A, 50/60 Hz Output: 24VDC (3.54A)

5.3 Generator specifications

(1) Generator specifications (0909FCB)

Equipment	Model	Manufacture	Specification		
X-ray generator	HTC-35B	Poskom Co.,Ltd.		Large-focus	Small-focus
			kVp	40-110	40-110
			mA	25-40	0.2-10
			KW (Power)	3.5	1.1
X-ray tube	DF-151SBR	Toshiba electron Co.,Ltd.	-		

(2) Generator specifications (1212FCA)

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 Predicate Device

Characteristic	Proposed Device		Predicate Device	Similarity
Manufacturer	**Rayence Co.,Ltd.**		**Rayence Co.,Ltd.**	
Product Name	0909FCB	1212FCA	1212FCA	
Feature				-
510(k) number	K212753	K212753	K202722	-
Intended Use	Digital Flat Panel X-Ray Detector is indicated for digital imaging solution designed for human anatomy including head, neck, cervical spine, arm, leg and peripheral (foot, hand, wrist, fingers, etc.). It is intended to replace film based radiographic diagnostic systems and provide a case diagnosis and treatment planning for physicians and other health care professionals. Not to be used for mammography.	Digital Flat Panel X-Ray Detector is indicated for digital imaging solution designed for human anatomy including head, neck, cervical spine, arm, leg and peripheral (foot, hand, wrist, fingers, etc.). It is intended to replace film based radiographic diagnostic systems and provide a case diagnosis and treatment planning for physicians and other health care professionals. Not to be used for mammography.	1212FCA is indicated for digital imaging solution designed for human anatomy including head, neck, cervical spine, arm, leg and peripheral (foot, hand, wrist, fingers, etc.). It is intended to replace film based radiographic diagnostic systems and provide a case diagnosis and treatment planning for physicians and other health care professionals. Not to be used for mammography.	Same
Detector Type	CMOS Photodiode Array	IGZO TFT + PIN type photodiode	IGZO TFT + PIN type photodiode	0909FCB and 1212FCA has different detector type but it is same indirect conversion method of Radiation image detection
Scintillator	CsI:Tl	CsI:Tl	CsI:Tl	Same
Imaging Area	9 x 9 inches	12 x 12 inches	12 x 12 inches	-
Total Pixel matrix	2304×2256 (1x1) 1152×1128 (2×2)	1536 X 1536 (1x1) 768 X 768 (2x2)	1536 X 1536 (1x1) 768 X 768 (2x2)	Similar

Pixel pitch	90 (1x1) 180 (2×2)		194 µm (1x1) 388 µm (2x2)		194 µm (1x1) 388 µm (2x2)		Similar
A/D conversion	16 bits		14 / 16 bit		14 / 16 bit		Similar
Frame rate	Camera link (Base)	15 fps (1x1) 30 fps (2x2)	GigE	18 (1x1) 36 (2x2)	GigE	18 (1x1) 36 (2x2)	GigE cable type is same. 0909FCB has additional camera link type.
	Camera link (Medium)	30 fps (1x1) 30 fps (2x2)					
	GigE	10 fps (1x1) 30 fps (2x2)					
MTF	1.0 lp/mm, 0.689		0.1 lp/mm, 0.527		0.1 lp/mm, 0.527		Similar
	1.5 lp/mm, 0.512		1 lp/mm, 0.327		1 lp/mm, 0.327		
	2.0 lp/mm, 0.394		2 lp/mm , 0.210		2 lp/mm , 0.210		
	2.5 lp/mm, 0.274		2.5 lp/mm , 0.136		2.5 lp/mm , 0.136		
DQE (0)	0.581		0.778		0.778		Similar
Preview time	≤2 seconds		≤2 seconds		≤2 seconds		Same
Data output	RAW *The RAW files are convertible into DICOM 3.0 by console S/W		RAW *The RAW files are convertible into DICOM 3.0 by console S/W		RAW *The RAW files are convertible into DICOM 3.0 by console S/W		Same
Dimensions	245.0 X 245.0 X 55.0mm		334.0 x 326.0 x 49.9 mm		334.0 x 326.0 x 49.9 mm		Similar
Weight	3.2 kg		3.4 kg		3.4 kg		Similar

5.5 Comparison with Reference Device

Characteristic	Proposed Device		Reference	Similarity
Manufacturer	**Rayence Co.,Ltd.**		**Rayence Co.,Ltd.**	
Product Name	0909FCB	1212FCA	1717FCC	
Feature				-
510(k) number	K212753	K212753	K210985	-
Intended Use	Digital Flat Panel X-Ray Detector is indicated for digital imaging solution designed for human anatomy including head, neck, cervical spine, arm, leg and peripheral (foot, hand, wrist, fingers, etc.). It is intended to replace film based radiographic diagnostic systems and provide a case diagnosis and treatment planning for physicians and other health care professionals. Not to be used for mammography.	Digital Flat Panel X-Ray Detector is indicated for digital imaging solution designed for human anatomy including head, neck, cervical spine, arm, leg and peripheral (foot, hand, wrist, fingers, etc.). It is intended to replace film based radiographic diagnostic systems and provide a case diagnosis and treatment planning for physicians and other health care professionals. Not to be used for mammography.	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.	Similar 1717FCC is large size of detector therefore it can use whole human anatomy for digital imaging solution. In case of 0909FCB and 1212FCA are small size of detector therefore it can use for human anatomy including head, neck, cervical spine, arm, leg and peripheral (foot, hand, wrist, fingers, etc.).
Detector Type	CMOS Photodiode Array	IGZO TFT + PIN type photodiode	a-Si TFT + PIN type photodiode IGZO TFT + PIN type photodiode (option)	0909FCB and 1717FCC has different detector type but it is same indirect conversion method of Radiation image detection
Scintillator	CsI:Tl	CsI:Tl	CsI:Tl	Same
Imaging Area	9 x 9 inches	12 x 12 inches	17 x 17 inches	-
Total Pixel matrix	2304×2256 (1x1) 1152×1128 (2×2)	1536 X 1536 (1x1) 768 X 768 (2x2)	3072 X 3072 (1x1) 1536 X 1536 (2x2) 1024 X 1024 (3x3)	Similar

					768 X 768 (4x4)		
Pixel pitch	90 (1x1) 180 (2×2)		194 µm (1x1) 388 µm (2x2)		140 (1x1) 280 (2x2) 420 (3x3) 560 (4x4)		Similar
A/D conversion	16 bits		14 / 16 bit		14 / 16 bits		Similar
Frame rate	Camera link (Base)	15 fps (1x1) 30 fps (2x2)	GigE	18 (1x1) 36 (2x2)	Camera link	9 fps (1x1) 30 fps (2x2) 45 fps (3x3) 60 fps (4x4)	-GigE cable type is same. -0909FCB and 1717FCC have additional camera link type and 5GigE type.
	Camera link (Medium)	30 fps (1x1) 30 fps (2x2)			GigE	6 fps (1x1) 25 fps (2x2) 45 fps (3x3) 60 fps (4x4)	
	GigE	10 fps (1x1) 30 fps (2x2)			5GigE	15 fps (1x1) 30 fps (2x2) 45 fps (3x3) 60 fps (4x4)	
MTF	1.0 lp/mm, 0.689		0.1 lp/mm, 0.527		1.0 lp/mm, 0.535		Similar
	1.5 lp/mm, 0.512		1 lp/mm, 0.327		2.0 lp/mm, 0.220		
	2.0 lp/mm, 0.394		2 lp/mm , 0.210		3.0 lp/mm, 0.099		
	2.5 lp/mm, 0.274		2.5 lp/mm , 0.136		3.5 lp/mm, 0.073		
DQE (0)	0.581		0.778		Typ. 0.751		Similar
Preview time	≤2 seconds		≤2 seconds		≤2 seconds		Same
Data output	RAW *The RAW files are convertible into DICOM 3.0 by console S/W		RAW *The RAW files are convertible into DICOM 3.0 by console S/W		RAW *The RAW files are convertible into DICOM 3.0 by console S/W		Same
Dimensions	245.0 X 245.0 X 55.0mm		334.0 x 326.0 x 49.9 mm		470 x 470 x 50 mm		Similar
Weight	3.2 kg		3.4 kg		6.0 kg		1717FCC is large size of detector, therefore it is heavy than subject devices.

6. Summary of Performance Testing

<0909FCB>

0909FCB Digital Flat Panel X-Ray Detector has the same indications for use, the same scintillator material (CsI:Tl) and the same risk analysis characteristics compared to 1212FCA, the predicate devices (K202722). 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 0909FCB and 1212FCA, the images obtained with 0909FCB and 1212FCA were equivalent quality for the same view obtained from a similar patient with the 1212FCA.

The soft tissues on extremity films were seen with similar clarity for 0909FCB and 1212FCA. There was 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 (0909FCB), and the predicate device (1212FCA), 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. 0909FCB demonstrated equivalent or better performance in terms of MTF and DQE compared to 1212FCA, the predicate device, at all spatial frequencies.

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 will conform with all labeling requirements as per 21 CFR Subchapter J.

<1212FCA>

1212FCA Digital Flat Panel X-Ray Detector, the subject device, is identical to 1212FCA (K202722). 1212FCA has similar indications for use, the same scintillator material (CsI:Tl), the same generator specifications and the same risk analysis characteristics compared to 1717FCC (K210985), the reference devices. 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 non-clinical test report contains the MTF, DQE and NPS performance test comparison between 1212FCA, the subject device, and 1717FCC (K210985), the predicate device, 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. 1212FCA demonstrated equivalent performance in terms of MTF and better performance in terms of DQE compared to 1717FCC (K210985), the predicate device, at all spatial frequencies.

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.

7. Summary for any testing and reference guidance:

- 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)
- EMC testing were conducted in accordance with standard IEC 60601-1-2: 2014.
- 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 efficiency Detectors used in radiographic imaging
- 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, 0909FCB, 1212FCA demonstrated equivalent or better performance compared to the predicate and reference devices. Therefore, Rayence claims the substantial equivalency between the subject device and the predicate device in terms of diagnostic image quality about safety and effectiveness.