March 7, 2024

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

Re: K240371
Trade/Device Name: 0909FCC, 0909FCC-HS
Regulation Number: 21 CFR 892.1680
Regulation Name: Stationary x-ray system
Regulatory Class: Class II
Product Code: MQB, JAA
Dated: January 19, 2024
Received: February 7, 2024

Dear Mr. Dave 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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,

Lu Jiang

Lu Jiang, 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: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K240371

Device Name
0909FCC, 0909FCC-HS

Indications for Use *(Describe)*

"0909FCC and 0909FCC-HS are indicated for digital imaging solution designed including head, neck, cervical spine, arm, leg and peripheral (foot, hand, wrist, fingers, etc.). The detectors are intended to replace the x-ray imager on film based radiographic diagnostic systems. 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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(k) Summary
(K240371)

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

1. Date 510k summary prepared: **January** 19,2024

2. 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. Inhwan Bang / QMR / +82-31-8015-6427
Official Correspondent:	Mr. Dave Kim, MBA **(**davekim@mtechgroupllc.com**)**
	Mtech Group LLC
Address:	7505 Fannin St. 610, Houston, TX 77054
Telephone:	+1-713-467-2607

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

3. Trade/proprietary name **:** 0909FCC, 0909FCC-HS

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

4. Primary Predicate Device :

Trade/Device Name	:1212FCA
Common Name	: Digital Flat Panel X-ray Detector
510(k) Number	: K212753
Regulation Number	: 21 CFR 892.1680
Regulation Name	: Stationary X-ray System

Regulatory Class	: Class II
Product Code	: MQB, JAA

5. Device Description

0909FCC and 0909FCC-HS are digital solid state X-ray detectors based on flat-panel technology. This radiographic image detector and processing unit consists of a scintillator coupled to 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 Lite) for a radiographic diagnosis and analysis. 0909FCC is a basic model. 0909FCC-HS is identical with a basic model except for marking of sheet not related to safety.
0909 FCC and 0909 FCC-HS are intended to capture dynamic images. The Xmaru RF lite imaging software is included in the system but the computer that receives the digital images is not provided with the system.
0909FCC and 0909FCC-HS are compatible with the X-ray generator, HTC-35B by Poskom Co.,Ltd, which is not provided with the system.

6. Indication for use

0909FCC and 0909FCC-HS are indicated for digital imaging solution designed including head, neck, cervical spine, arm, leg and peripheral (foot, hand, wrist, fingers, etc.). The detectors are intended to replace the x-ray imager on film based radiographic diagnostic systems. Not to be used for mammography.

7. Summary of Design Control Risk management

0909FCC and 0909FCC-HS digital X-ray detectors are modifications of the 1212FCA (K212753). 0909FCC and 0909FCC-HS were developed for the purpose of retrofitting the stationary X-ray system with a film detector. 0909FCC and 0909FCC-HS are slightly smaller than 1212FCA (K212753).
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.

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

0909FCC and 0909FCC-HS detectors described in this 510(k) have the same indications for use and similar technical characteristics as its predicate devices, 1212FCA(K212753).

8.1 Scintillator layer

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

	Proposed	**Predicate**
CsI (Cesium Iodide)	0909FCC, 0909FCC-HS	1212FCA

8.2. Power source : ATM065T-P240 or AHM85PS24

		Proposed 0909FCC, 0909FCC-HS	**Predicate** 1212FCA
Power	Type	Power adapter	Power adapter
	Model name	AHM85PS24	AHM85PS24
	Dimension	150 X 64 X 37 (cable length: 900 mm)	150 X 64 X 37 (cable length: 900 mm)
	Weight	0.4kg	0.4kg
	Rating	Input: 100-240 Vac, 1.0 A, 50/60 Hz Output: Typ. 24 VDC, 3.54 A	Input: 100-240 Vac, 1.0 A, 50/60 Hz Output: 24VDC (Max 3.54A)

		Proposed 0909FCC, 0909FCC-HS	**Predicate** 1212FCA
Power	Type	Power adapter	Power adapter
	Model name	ATM065T-P240	AHM85PS24
	Dimension	119 X 60 X 36 (cable length: 1500 mm)	150 X 64 X 37 (cable length: 900 mm)
	Weight	0.31kg	0.4kg
	Rating	Input: 100-240 Vac, 1.6 A, 50/60 Hz Output: Typ. 24 VDC, 2.71 A	Input: 100-240 Vac, 1.0 A, 50/60 Hz Output: 24VDC (Max 3.54A)

8.3 Comparison with Predicate Device

Characteristic	Proposed Device		Predicate Device		Similarity
Manufacturer	**Rayence Co.,Ltd.**		**Rayence Co.,Ltd.**		
510k No:	K240371		K212753		
Product Name	0909FCC	0909FCC-HS	1212FCA		
Feature					
510(k) number	-		K212753		
Indications for Use	0909FCC and 0909FCC-HS are indicated for digital imaging solution designed including head, neck, cervical spine, arm, leg and peripheral (foot, hand, wrist, fingers, etc.). The detectors are intended to replace the x-ray imager on film based radiographic diagnostic systems. 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	IGZO TFT + PIN type photodiode		IGZO TFT + PIN type photodiode		Same
Scintillator	CsI:Tl		CsI:Tl		Same
Imaging Area	9 x 9 inches		12 x 12 inches		Similar
Effective Pixel matrix	1464 X 1464 (1x1 Full resolution) 732 X 732 (2x2 binning)		1500 X 1500 (1x1) 750 X 750 (2x2)		Same
Pixel pitch	140 µm (Full resolution) 280 µm (2x2 binning)		194 µm (1x1) 388 µm (2x2)		Similar
A/D conversion	14/16 bits		14 / 16 bit		Same
Frame rate	5GigE	29 @ (1x1) 58 @ (2x2)	GigE	18 (1x1) 36 (2x2)	Similar
Max. resolution (lp/mm)	3.57 lp/mm (full resolution) 1.79 lp/mm (2x2 binning)		2.58 lp/mm (full resol.) 1.29 lp/mm (2x2)		
MTF (1.0	0.497		0.513		Similar

lp/mm)			
DQE (0.5)	0.789	0.753	Similar
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	Same
Dimensions	280.0 X 280.0 X 45.0mm	334.0 x 326.0 x 49.9 mm	Similar
Weight	2.8 kg	3.4 kg	Similar
Imaging Software	XmaruRF Lite (provided with 0909FCC and 0909FCC-HS)	-	-

9. Summary of Performance Testing

0909FCC and 0909FCC-HS Digital Flat Panel X-Ray Detectors have the same indications for use, the same scintillator material (CsI:Tl) coupled to Indium Gallium Zinc Oxide (IGZO) on TFT sensor, the same generator specifications and the same risk analysis characteristics compared to 1212FCA, the predicate devices (K212753). 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 for the subject device was prepared and submitted to FDA to demonstrate the substantial equivalency of the subject device performance compared to the predicate device.

The results of bench testing indicate substantial equivalence of the subject detectors 0909FCC, 0909FCC-HS and the predicate device.

The non-clinical test report contains the MTF, DQE and NPS performance test comparison between the subject device (0909FCC), 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. 0909FCC demonstrated equivalent or better performance in terms of MTF and DQE compared to 1212FCA, the predicate device, at all spatial frequencies.

Based on non-clinical consideration evaluation, substantial equivalence between the subject device and predicate device in terms of diagnostic image quality has been demonstrated.

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.

10. Summary for any testing and reference guidance:

- Electrical, mechanical, environmental safety and performance testing according to standard IEC 60601-1: 2020 (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: 2020
- IEC 62220-1 Ed 1.0 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

11. Conclusions:

In accordance with the performance outcomes, 0909FCC and 0909FCC-HS demonstrated equivalent or better performance compared to 1212FCA(K212753). Therefore, Rayence claims that based on non-clinical consideration evaluation, substantial equivalence between the subject device and predicate device in terms of diagnostic image quality has been demonstrated.