July 31, 2026

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

Re: K253800
Trade/Device Name: 0909FCE, 0909FCE-HS
Regulation Number: 21 CFR 892.1680
Regulation Name: Stationary X-Ray System
Regulatory Class: Class II
Product Code: MQB, JAA
Dated: June 25, 2026
Received: June 30, 2026

Dear 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 (the 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 available 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 Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (Preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Management System Regulation (QMSR) (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

FDA Digitally signed by GABRIELA M. RODAL -S for

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)*
K253800

Device Name
0909FCE, 0909FCE-HS

Indications for Use *(Describe)*
0909FCE and 0909FCE-HS are indicated for digital imaging solution designed 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.

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

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

1. 510(k) Summary : K253800

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: **June 25, 2026**

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:	+82-31-8015-6305
Contact person:	Mr. Sung Woo Jung / QMR/ +82-31-8015-6305
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:

Trade/proprietary name

Trade/Device Name	: 0909FCE, 0909FCE-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

Primary Predicate Device :

Trade/Device Name	: 0909FCC, 0909FCC-HS
Common Name	: Digital Flat Panel X-ray Detector
510(k) Number	: K240371
Regulation Number	: 21 CFR 892.1680
Regulation Name	: Stationary X-ray System

Regulatory Class	: Class II
Product Code	: MQB, JAA

2. Device Description

0909FCE and 0909FCE-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 C) for a radiographic diagnosis and analysis. 0909FCE is a basic model. 0909FCE-HS is identical with a basic model except for marking of sheet not related to safety.

3. Indication for use

0909FCE and 0909FCE-HS are indicated for digital imaging solution designed 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

0909FCE and 0909FCE-HS digital X-ray detectors are modifications of the 0909FCC and 0909FCC-HS (K240371). 0909FCE and 0909FCE-HS were 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:

0909FCE and 0909FCE-HS detectors described in this 510(k) have the same indications for use and similar technical characteristics as its predicate devices, 0909FCC and 0909FCC-HS(K240371).

5.1 Scintillator layer

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

	Proposed	Predicate
CsI (Cesium Iodide)	0909FCE, 0909FCE-HS	0909FCC, 0909FCC-HS

5.2. Power source : AHM85PS24

		Proposed 0909FCE, 0909FCE-HS	Predicate 0909FCC, 0909FCC-HS
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)

5.3 Generator specifications

(1) X-ray Generator specifications

Equipment	Model	Manufacture	Specification		
				Large-focus	Small-focus
X-ray generator	HTC-5500A	Poskom Co.,Ltd.	kVp	40-120	40-120
			mA	32-100	0.2-8 (Normal) 0.2-10 (Pulse) 20 (Boost)
			KW (Power)	5.5	0.96
X-ray tube	XD56-517	Hangzhou Wandong Electron Co.,Ltd	-		

5.4 Comparison with Predicate Device

Characteristic	Proposed Device		Predicate Device		Similarity
Manufacturer	Rayence Co.,Ltd.		Rayence Co.,Ltd.		
Product Name	0909FCE	0909FCE-HS	0909FCC	0909FCC-HS	
Feature					
510(k) number	K253800		K240371		
Indications for Use	0909FCE and 0909FCE-HS are indicated for digital imaging solution designed 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.		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.). 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		9 x 9 inches		Same
Effective Pixel matrix	1504 X 1488 (Full resolution) 752 X 744 (2x2 binning)		1464 X 1464 (1x1 Full resolution) 732 X 732 (2x2 binning)		Similar
Pixel pitch	140 (Full resolution) 280 (2x2 binning)		140 µm (Full resolution) 280 µm (2x2 binning)		Same
A/D conversion	14/16 bits		14/16 bits		Same
Frame rate	5GigE	30 @ (1x1) 60 @ (2x2)	5GigE	29 @ (1x1) 58 @ (2x2)	Similar
*MTF (*1.0 lp/mm)	0909FCE : 0.637 0909FCE-HS : 0.482		0.497		Similar
DQE (0.5)	0909FCE : 0.602 0909FCE-HS : 0.765		0.789		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	245 x 247 x 46 mm	280.0 X 280.0 X 45.0mm	Similar
Weight	3.7 kg	2.8 kg	Similar
Software(Option)	Xmaru C	Xmaru RF Lite	-
Generator Control	Yes	No	Different
Operation Software	Microsoft Windows 11(64 bit) Professional or higher	Microsoft Windows 10(64 bit) Professional or higher	Different
Image acquisition capabilities and workflow	Detector setup, X-ray exposure, acquisition, processing, display. Generator setup function have been added.	Detector setup, X-ray exposure, acquisition, processing, display	Similar
Image Processing	Brightness, contrast, sharpness, windowing, binning, protocol controls. Updated to enhance image processing performance(ROI/ABC controls, auto windowing).	Brightness, contrast, sharpness, windowing, binning, protocol controls	Similar
User Interface and Display Functions	Viewer display, toolbar, protocol list, rotate, flip, invert, reset, zoom, language/settings The existing single-viewer user interface has been updated to Live Image and Saved Image user interface. And Worklist and StudyList have been added to enhance user convenience.	Viewer display, toolbar, protocol list, rotate, flip, invert, reset, zoom, language/settings	Similar
DICOM Functions	DICOM server/printer and AE title/port configuration Updated to improve multiple functions(PACS Worklist, multi-destination send, character set),	DICOM server/printer and AE title/port configuration	Similar
Network	100MBit or 1GBit	100MBit or 1GBit	Same
Data storage and management capabilities	RAW file storage, Raw folder, HDD capacity, setting persistence Update to enhance data management function(database managements, CSV export)	RAW file storage, Raw folder, HDD capacity, setting persistence	Similar
Software Design	C#/.NET Framework 4.8 and WPF	C#/.NET Framework 4.5.1 and WPF	Similar
Processor	Intel® Core™ i5 or higher	Intel® Core™ i5 or higher	Same
RAM	16GB or more	8GB or 16GB(optimized)	Similar
Hard Disk	500GByte or higher	200GB or higher	Similar
Image Formatting	Supports documented image export/formatting functions, including JPG, PNG, GIF, BMP, DICOM, and layout formats such as 1x1, 1x2, 2x1, 2x2, and 3x3.	Supports documented image export/formatting functions, including JPG, PNG, GIF, BMP, DICOM, and layout formats such as 1x1, 1x2, 2x1, 2x2, and 3x3.	Same
Processing speed	Supports image display within 3 seconds.	Supports image display within 3 seconds.	Same

and performance metrics			
Cybersecurity	Includes basic user authentication and access control Updated to enhance the multiple functions(auto logoff, password rules and input validation).	Includes basic user authentication and access control	Similar

6. Summary of Performance Testing

0909FCE and 0909FCE-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 0909FCC and 0909FCC-HS, the predicate devices(K240371). 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.

Upon review of the plain radiographs taken with 0909FCE and 0909FCC, both demonstrated good image quality.
In conclusion, both 0909FCE and 0909FCC have demonstrated sufficient image quality which will provide aid for diagnostic purposes

The non-clinical test report contains the MTF, DQE and NPS performance test comparison between the subject device, and 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. 0909FCE demonstrated equivalent or better performance in terms of MTF and DQE compared to 0909FCC and 0909FCC-HS, 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 software, Xmaru C, is an updated version of Xmaru RF Lite with enhanced performance features based on the existing functions of Xmaru RF Lite. The identified differences between Xmaru C and Xmaru RF Lite are related to the operating system version and the integration with the generator.

The updated functions and enhanced features implemented in Xmaru C were evaluated through software validation activities, and the results demonstrated that the functions operate as intended.(Ref: Software Validation Report)

The software, Xmaru C, is an updated version of Xmaru RF Lite with enhanced performance features based on the existing functions of Xmaru RF Lite. The identified differences between Xmaru C and Xmaru RF Lite are related to the operating system version and the integration with the generator.

The operating system difference is related to the Windows version. Xmaru C supports Windows 11, which is a currently supported operating system by Microsoft. Compared to Xmaru RF Lite, which supports Windows 10, Xmaru C provides a supported and stable operating environment based on the current Microsoft-supported platform.

The difference related to generator integration was evaluated through risk management activities and software verification and validation activities. Appropriate risk control measures were implemented to address potential risks associated with the added generator interface functionality.

Based on the risk evaluation and verification activities, the identified differences do not introduce new unacceptable risks and do not raise new questions of safety or effectiveness.

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.

7. 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 Content of Premarket Submissions for Device Software Functions".
- Pediatric Information for X-ray Imaging Device Premarket Notifications
- Cybersecurity in Medical Devices: Quality Management System Considerations and Content of Premarket Submissions

8. Conclusions:

In accordance with the performance outcomes, 0909FCE and 0909FCE-HS demonstrated equivalent or better performance compared to 0909FCC and 0909FCC-HS(K240371). Therefore, Rayence claims the substantial equivalency between the subject device and the predicate device in terms of diagnostic image quality about safety and effectiveness.