September 9, 2024

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

Re: K242394
Trade/Device Name: Digital Flat Panel X-ray Detector
(1717WCE, 1717WCE-HR, 1717WCE-HS, 1717WCE-GF)
Regulation Number: 21 CFR 892.1680
Regulation Name: Stationary x-ray system
Regulatory Class: Class II
Product Code: MQB
Dated: May 30, 2024
Received: August 13, 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 (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 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 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 systems (QS) regulation (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,

Lu Jiang

Lu Jiang, Ph.D.
Assistant Director
Diagnostoc X-Ray Systems Team
DHT8B: Division of Radiologic 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)*
K242394

Device Name
Digital Flat Panel X-Ray Detector (1717WCE, 1717WCE-HR, 1717WCE-HS, 1717WCE-GF)

Indications for Use *(Describe)*

Digital Flat Panel X-Ray Detector 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
K242394

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: July 30, 2024

Submitter's Name : Rayence Co., Ltd.
Submitter's Address: 14, Samsung 1-ro 1-gil, Hwaseong-si, Gyeonggi-do, Korea
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Name of the device, including the trade or proprietary name if applicable, the common or usual name and the classification name, if known:

Subject Device:

Trade/proprietary name	**:** Digital Flat Panel X-ray Detector (1717WCE, 1717WCE-HR, 1717WCE-HS, 1717WCE-GF)
Regulation Number	: 21 CFR 892.1680
Regulation Name	: Stationary X-ray System
Regulatory Class	: Class II
Product Code	: MQB

Predicate Device :

Trade/Device Name:	: Digital Flat Panel X-ray Detector (Model: 1417WCE, 1417WCE-HR, 1417WCE-HS, 1417WCE-GF)
510(k) Number	: K231467
Regulation Number	: 21 CFR 892.1680
Regulation Name	: Stationary X-ray System
Regulatory Class	: Class II

Product Code : MQB

2. Device Description

1717WCE, 1717WCE-HR, 1717WCE-HS, 1717WCE-GF X-ray detectors, are wired/wireless digital solid state X-ray detectors that are based on flat panel technology. The wireless LAN (IEEE 802.11 n/ac) communication signals images captured to the system and improves the user operability through high speed processing. These radiographic image detectors are processing unit consist of a scintillator coupled to an TFT sensor. The flat-panel detectors need to be integrated with an x-ray generator (not part of the submission), so it can be utilized to capture and digitize x-ray images for radiographic diagnosis.

1717WCE, 1717WCE-HR, 1717WCE-HS, 1717WCE-GF includes the software (firmware) of basic level of concern. It's the same Image Acquisition and Operating Software used for the predicate device is used but modified to include additional detector models in comparison with the predicate device. Full software documentation has been submitted, as well as the necessary sections to demonstrate device cybersecurity.

The RAW files can be further processed as DICOM compatible image files by separate consol SW (K190866, XmaruView V1 / Rayence Co.,Ltd) for a radiographic diagnosis and analysis.

1717WCE is the basic model. 1717WCE-HR is identical with the basic model except for pixel pitch not related to safety. 1717WCE-HS is identical with the basic model except for marking of sheet. 1717WCE-GF is identical with the basic model except for case color and pixel pitch.

Model	Color	Pixel pitch
1717WCE	White	140um
1717WCE-HR	White	99.9um
1717WCE-GF	Black	99.9um
1717WCE-HS	White & Green Mark	140um

3. Indication for use

Digital Flat Panel X-Ray Detector 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

1717WCE, 1717WCE-HR, 1717WCE-HS, 1717WCE-GF digital X-ray detectors are modification of 1417WCE (K231467).

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:

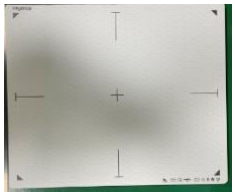
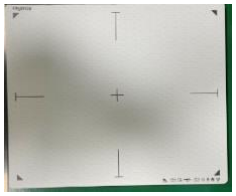
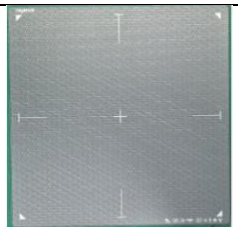
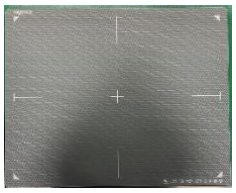
Detector described in this 510(k) has the same indications for use and similar technical characteristics as its predicate devices (K231467).

5.1 Scintillator layer

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

Scintillator Type	Proposed	Predicate
CsI (Cesium Iodide)	1717WCE, 1717WCE-HR, 1717WCE-HS, 1717WCE-GF	1417WCE, 1417WCE-HR, 1417WCE-HS, 1417WCE-GF (K231467)

5.2 Comparison table

	Subject device		Predicate device		
Model	1717WCE 1717WCE-HS	1717WCE-HR 1717WCE-GF	1417WCE 1417WCE-HS	1417WCE-HR 1417WCE-GF	**Similarity**
Feature	 1717WCE	 1717WCE-HR	 1417WCE	 1417WCE-HR	-
	 1717WCE-HS	 1717WCE-GF	 1417WCE-HS	 1417WCE-GF	
Intended Use	Digital Flat Panel X-Ray Detector 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.		Digital Flat Panel X-Ray Detector 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.		Same
Detector Type	Amorphous Silicon, TFT	Amorphous Silicon, TFT Indium Gallium Zinc Oxide with TFT (Single panel)	Amorphous Silicon, TFT		Similar
Scintillator	CsI:Tl		CsI:Tl		Same
Imaging Area	17 x 17 inches		14 x 17 inches		Similar
Pixel pitch	140 μm	99.9 μm	140 μm	100 μm	Same
Total Pixel matrix	3072 X 3072	4302 X 4302	2500 X 3052	3534 X 4302	Similar
Resolution	3.57 lp/mm	5.00 lp/mm	3.57 lp/mm	5.00 lp/mm	Same
DQE (@1lp/mm)	Typ.69%	Typ.62 %	Typ.63%	Typ.62 %	Similar
MTF (@1lp/mm)	Typ 62%	Typ 66%	Typ 66%	Typ 61%	Similar
A/D conversion	16 bits		16 bits		Same
Dimensions	460 X 460 X 15mm		384 X 460 X 15mm		Similar
Weight	3.3 kg (incl. 1 battery)		2.7 kg (incl. 1 battery)		Similar
Viewer Software (option)	XmaruView V1 (K190866/ Rayence Co.,Ltd)		XmaruView V1 (K190866/ Rayence Co.,Ltd)		Same

6. Summary of Performance Testing

1717WCE, 1717WCE-HR, 1717WCE-HS, 1717WCE-GF X-ray detectors have same indications for use, scintillator material (CsI:T1), general specifications and same risk analysis characteristics compared to the predicate device, 1417WCE (K231467). 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 1717WCE, 1717WCE-HR, 1717WCE-HS, 1717WCE-GF and 1417WCE images obtained equivalent quality for the same view obtained from a similar patient .

Upon review of the plain radiographic images taken with 1717WCE_99.9um and the 1417WCE_100um, 1717WCE_99.9um has presented overall a better image quality of the same anatomical position in the separate patients. The anatomical structures, both bony and soft tissues of the upper and lower extremities were seen with better clarity in the 1717WCE_99.9um. The disadvantages of 1417WCE_100um were decreased sharpness, more overexposed appearance, and higher noise level in general. In conclusion, 1717WCE_99.9um had a clearer view than 1417WCE_100um, which will provide aid for diagnosis purposes.

Upon review of the plain radiographic images taken with 1717WCE_140um and the 1417WCE_140um, 1717WCE_140um has presented overall a better image quality of the same anatomical position in the separate patients. The anatomical structures, both bony and soft tissues of the upper and lower extremities were seen with better clarity in the 1717WCE_140um. The disadvantages of 1417WCE_140um were less sharpness, more over exposed appearance and higher noise level in general. In conclusion, 1717WCE_140um had a clearer view than 1417WCE_140um, which will provide aid for diagnosis purposes.

In conclusion, both 1717 WCE_140 um and 1717 WCE_99.9um have demonstrated sufficient image quality which will provide aid for diagnostic purposes.

The Radio Frequency Wireless Coexistence Test was conducted for the subject device. 1717WCE

wireless implements IEEE802.11 a/g/n to establish bi-directional communication between the X-ray detector and Access point. 1717WCE wirelss has been found capable of transmitting data within twenty seconds in a normal deployment. The wireless transmission feature is unchanged from the predicate device.

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.

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.

7. Summary for any testing and reference guidance:

- Electrical, mechanical, environmental safety and performance testing according to standard IEC 60601-1:2005, AMD1:2012, AMD2:2020 (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: 2014+AMD1:2020
- IEC 62220-1:2015 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

8. Conclusions:

In accordance with the performance outcomes, 1717WCE, 1717WCE-HR, 1717WCE-HS, 1717WCE-GF X-ray detectors demonstrated equivalent or better performance compared to 1417WCE. Therefore, Rayence claims the substantial equivalency between the subject device and the predicate device in terms of diagnostic image quality about safety and effectiveness.