June 21, 2023

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

Re: K231467
Trade/Device Name: 1417WCE, 1417WCE-HR, 1417WCE-HS, 1417WCE-GF
Regulation Number: 21 CFR 892.1680
Regulation Name: Stationary x-ray system
Regulatory Class: Class II
Product Code: MQB
Dated: May 17, 2023
Received: May 22, 2023

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,

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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K231467

Device Name
1417WCE, 1417WCE-HR, 1417WCE-HS, 1417WCE-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.

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."

510(k) Summary

K231467

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

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@mtechgroupllc.com**)**
Address:	7505 Fannin St. Ste 610, 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 **:** 1417WCE, 1417WCE-HR, 1417WCE-HS, 1417WCE-GF

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

Predicate Device :

Trade/Device Name	: 1417WCC
Common Name	: Digital Flat Panel X-ray Detector
510(k) Number	: K171418
Regulation Number	: 21 CFR 892.1680
Regulation Name	: Stationary X-ray System
Regulatory Class	: Class II
Product Code	: MQB

2. Device Description

1417WCE, 1417WCE-HR, 1417WCE-HS, 1417WCE-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 a-Si TFT sensor. These devices need to be integrated with a static radiographic imaging system. It can be utilized to capture and digitalize X-ray images for radiographic diagnosis.

The revised 510k Summary specified that 1417WCE, 1417WCE-HR, 1417WCE-HS, 1417WCE-GF includes the software (firmware) of MODERATE level of concern. It's the same Image Acquisition and Operating Software used for the predictive device is used but modified to include additional detector models in comparison with the predicate device.

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. The imaging software XMaru View V1 is not part of the subject device.

1417WCE is the basic model. 1417WCE-HR is identical with the basic model except for the pixel pitch size. 417WCE-HS is identical with the basic model except for the case color. 1417WCE-GF is identical with the basic model except for the case color and the pixel pitch size. The differences are not safety related.

Model	Color	Pixel pitch
1417WCE	White	140um
1417WCE-HR	White	100um
1417WCE-GF	Black	100um
1417WCE-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

1417WCE, 1417WCE-HR, 1417WCE-HS, 1417WCE-GF digital X-ray detectors are modification of 1417WCC (K171418).

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 (K171418).

5.1 Scintillator layer

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

Scintillator Type	Proposed	Predicate
CsI (Cesium Iodide)	1417WCE, 1417WCE-HR, 1417WCE-HS, 1417WCE-GF	1417WCC_127 µm and1417WCC_140 µm

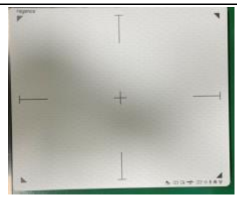
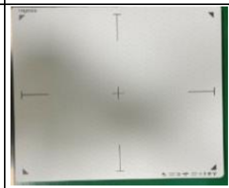
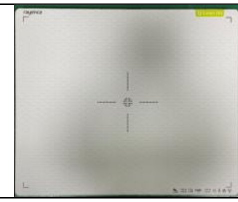
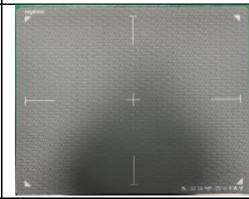
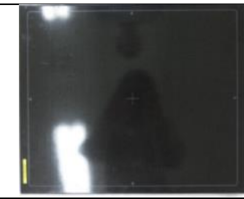
5.2 Power source

		Proposed 1417WCE, 1417WCE-HR, 1417WCE-HS, 1417WCE-GF	Predicate 1417WCC_127 µm and1417WCC_140 µm
Power	Type	Power supply	Power supply
	Model name	RP003A	RP003A
	Dimension	188 X 92 X 41.5	188 X 92 X 41.5
	Weight	0.5	0.5
	Rating	Input: 100-240VAC (50/60Hz) Output: 24VDC (Max 1.7A)	Input: 100-240VAC (50/60Hz) Output: 24VDC (Max 1.7A)

5.3 Recommended 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 table

	Subject device				**Predicate device**	
Model	1417WCE	1417WCE-HR	1417WCE-HS	1417WCE-GF	1417WCC	**Similarity**
Feature						–
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.	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.	Flat Panel 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	Amorphous Silicon, TFT	Amorphous Silicon, TFT	Amorphous Silicon, TFT	Same
Scintillator	CsI:Tl	CsI:Tl	CsI:Tl	CsI:Tl	CsI:Tl	Same
Imaging Area	14 x 17 inches	14 x 17 inches	14 x 17 inches	14 x 17 inches	14 x 17 inches	Same
Pixel matrix	140 type: 2500 X 3052	100 type: 3534 X 4302	140 type: 2500 X 3052	100 type: 3534 X 4302	127type: 3328 X 2816 140type: 2500 X 3052	Similar
Pixel pitch	140 µm	100µm	140 µm	100µm	127 µm, 140 µm	Similar
Resolution	140 type: 3.57 lp/mm	100 type: 5.00 lp/mm	140 type: 3.57 lp/mm	100 type: 5.00 lp/mm	127 type: 3.93 140 type: 3.57	Similar
DQE (@1lp/mm)	100µm : Typ. 62 % 140µm : Typ. 63%	100µm : Typ. 62 % 140µm : Typ. 63%	100µm : Typ. 62 % 140µm : Typ. 63%	100µm : Typ. 62 % 140µm : Typ. 63%	127µm : Typ. 59% 140µm : Typ. 61%	Similar
MTF (@1lp/mm)	100 : Typ 60% 140 : Typ 66%	100 : Typ 60% 140 : Typ 66%	100 : Typ 60% 140 : Typ 66%	100 : Typ 60% 140 : Typ 66%	127µm : Typ. 55% 140µm : Typ. 53%	Similar
A/D Conv	16 bits	16 bits	16 bits	16 bits	14 / 16 bits	Similar
Dimensions	384 X 460 X 15mm	384 X 460 X 15mm	384 X 460 X 15mm	384 X 460 X 15mm	460 X 384 X 15mm	Similar
Weight	≤ 2.7 kg	≤ 2.7 kg	≤ 2.7 kg	≤ 2.7 kg	3 (incl. battery)	Similar

6. Summary of Performance Testing

1417WCE, 1417WCE-HR, 1417WCE-HS, 1417WCE-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, 1417WCC (K171418). 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 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 1417WCE, 1417WCE-HR, 1417WCE-HS, 1417WCE-GF and 1417WCC images obtained equivalent quality for the same view obtained from a similar patient .

bony structure details of hands, fingers and feet had better clarity in the 1417WCE_100um as they showed sharper cortical lines which would be better in evaluating long bone fractures.
1417WCC_140um images showed sharper cortical lines and trabecular patterns with less image noise and overall better contrast.

In conclusion, both 1417 WCE_140 um and 1417 WCE_100 um 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.

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 62220-1:2015 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, 1417WCE, 1417WCE-HR, 1417WCE-HS, 1417WCE-GF X-ray detectors demonstrated equivalent or better performance compared to 1417WCC. Therefore, Rayence claims the substantial equivalency between the subject device and the predicate device in terms of diagnostic image quality about safety and effectiveness.