Rayence Co., Ltd
℅ Dave Kim
President
Mtech Group
7707 Fannin St. Ste. 200
HOUSTON TX 77054

June 21, 2021

Re: K202902
Trade/Device Name: 2430MCA with Xmaru W
Regulation Number: 21 CFR 892.1715
Regulation Name: Full-Field Digital Mammography System
Regulatory Class: Class II
Product Code: MUE, LLZ
Dated: May 14, 2021
Received: May 18, 2021

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 (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)*
k202902

Device Name

2430MCA with Xmaru W

Indications for Use *(Describe)*

The 2430MCA Digital Flat Panel X-Ray Detector is indicated for digital imaging solution designed for a mammographic system. It is intended to replace film or screen based mammographic systems in screening mammography.
Xmaru W is an integrated software solution indicated for use with the 2430MCA detector.

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
K202902

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

1. Date 510k summary prepared: May 18, 2021

2. Submitter's Information:

Name of sponsor	Rayence Co., Ltd.
Address	14, Samsung 1-ro 1-gil, Hwaseong-si, Gyeonggi-do, Korea
Telephone no.	+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, Houston, TX 77054
Telephone no.	+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:

Proposed Device :

	Detector (2430MCA)	Software (Xmaru W)
Trade/proprietary name	2430MCA with Xmaru W	
Common Name	Digital Flat Panel X-ray Detector	Radiological Image Processing System
Regulation Number	21 CFR 892.1715	21 CFR 892.2050
Regulation Name	Full-field digital mammography system	Picture archiving and communications system
Product Code	MUE	LLZ

Predicate Device :

	Detector (RSM 1824C)	Software (Rconsole1)
510(k) Number	K162670	
Applicant	DRTECH Corporation	
Trade/proprietary name	RSM 1824C with RConsloe1	
Common Name	Digital Flat Panel X-ray Detector	Radiological Image Processing System
Regulation Number	21 CFR 892.1715	21 CFR 892.2050
Regulation Name	Full-field digital mammography system	Picture archiving and communications system
Product Code	MUE	LLZ

3. Device Description

2430MCA is a digital mammography X-ray detector that is based on flat-panel technology. This mammographic image detector and processing unit consists of a CsI scintillator coupled to a CMOS sensor. This device needs to be integrated with a mammographic imaging system. It can be utilized to capture and digitalize X-ray images for mammographic screening.

The RAW files can be further processed as DICOM compatible image files by separate console SW, Xmaru W for a mammographic screening.

2430MCA detector is connected by wire to a viewing station via ethernet connection.

4. Indication for use

The 2430MCA Digital Flat Panel X-Ray Detector is indicated for digital imaging solution designed for a mammographic system. It is intended to replace film or screen based mammographic systems in screening mammography. Xmaru W is an integrated software solution indicated for use with the 2430MCA detector.

5. Summary of Design Control Risk management

The 2430MCA digital X-ray detector with Xmaru W is similar to the predicate device, RSM 1824C with Rconsole1 (K162670). 2430MCA is slightly larger than RSM 1824C with Rconsole1 (K162670). Biocompatibility test is not applicable because this device is mounted on the cassette or bucky stand of the mammography system and has no contact part with patients.

The risks and the hazardous impact of the device were analyzed with FMEA method. The specific risk control and protective measures to mitigate the device risks 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.

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

The 2430MCA digital flat panel X-ray detector in this 510(k) has the similar indications for use and similar technical characteristics as its predicate device, RSM 1824C with Rconsole1 (K162670).

6.1 Comparison table

Characteristic		Proposed Device	Predicate Device #1	
Manufacturer		**Rayence Co.,Ltd.**	**DRTECH Corporation**	
Product Name		2430MCA with Xmaru W	RSM 1824C with Rconsole1	
510(k) number		K202902	K162670	
Intended Use		The 2430MCA Digital Flat Panel X-Ray Detector is indicated for digital imaging solution designed for a mammographic system. It is intended to replace film or screen based mammographic systems in screening mammography. Xmaru W is an integrated software solution indicated for use with the 2430MCA detector.	The RSM 1824C is a detector indicated for use in screening and diagnostic mammography. The RConsole1 is an integrated software solution indicated for use with the RSM Series detectors.	Similar
Detector Type		CMOS Photodiode Array	TFT a-Si	different detector type but it is same indirect conversion method of Radiation image detection
Scintillator		CsI	CsI	Same
Image Area		231.8 X 304.0 mm	233.4 x 175.1mm	Similar
Pixel matrix		3312 X 4344 (Full resolution) 1656 X 2172 (2x2 binning)	3,072 x 2,304	Similar
Pixel pitch		70 μm (Full resolution) 140 μm (2x2 binning)	76 μm	Similar
DQE (%)	2.0 lp/mm	57.8	55.0	Similar
	5.0 lp/mm	26.4	25.1	
MTF	2.0 lp/mm	51.5	42.5	Similar
	5.0 lp/mm	12.5	9.9	
Data output		RAW *The RAW files are convertible into DICOM 3.0 by console S/W	DICOM 3.0	Same
Acquisition devices		Digital X-ray Detector	Digital X-ray Detector	Same

Software Function	Image viewing Image search Image storage Image annotation Image measurement Image processing Image stitch	Image viewing Image search Image storage Image annotation Image measurement Image processing Image stitch	Same

6.2 Scintillator layer

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

	Proposed	**Predicate**
CsI (Cesium Iodide)	2430MCA	RSM 1824C

6.3 Power source

	specification
Model name	RS1417
Dimension	188 X 92 X 41.5
Weight	0.5
Rating	Input: 100-240 Vac, 50/60 Hz Output: Typ. 24VDC (Max 1.7A)

6.4 Integrated system recommended specifications

1) X-ray Unit

- Source to image receptor distance (SID) focal-image distance of more than 600 mm

Manufacturer	K number	SID(mm)
Genoray	K103425	650
Instrumentarium AlphaST	K981641	600
Hologic Lorad M4	K030666	660

- A detector large enough to take an image without having to take multiple images of the compressed breast. (24 cm x 26 cm or larger)
- Optimizes the contrast of the entire breast image and makes the most of the limited Dynamic range of the display system.

2) X-ray Tube

Genoray = Beryllium Window, Lorad M4 = Beryllium, 0.8mm thickness (maximum)

• focal spot sizes.

- Typical target-filter combination (filter material and thickness, focal spot sizes)
- Bucky size: The actual size is not listed anywhere on the equipment. Its size must be enough to cover 24 cm x 30cm (10 in x 12 in) for a film cassette.

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	Target	Filter		Focal Spot	
	material	Material	Thickness (mm)	Small (mm) (General shooting)	Large (mm) (Zoom selected area)
Genoray (K103425)	Mo	Mo/AI	0.03/0.5	0.1	0.3
GE (K981641)	Mo/Rh	Mo/Rh	0.03/0.025	0.1	0.3
Hologic M4 (K030666)	Mo	Mo/Rh	0.03/0.025	0.1	0.3
Fujifilm (K133972)	Mo	Mo/Rh	0.03/0.025		
Simens (P140011)	Mo	Mo/Rh			

3) X-ray Generator

- The trade name and model: Generay MX-series, Hologic Lorad M4
- Anode material -> molybdenum
- Technique factors of x-ray generator

	Genoray (k103425)	alphaST(K981641)	Lorad M4(K030666)
Focal Spot (Large) (General shooting)	0.3 mm	0.3 mm	0.3 mm
Tube voltage	22-39 kVp	kVp	22-39 kVp
Max. tube current	85mA	70-100mA	60-80mA kV / Large 22-24 / 80 25-28 / 80 29-34 / 70 35 / 60
mAs	1-600mAs		3-400mAs
Focal Spot (Small) (Zoom selected area)	0.1 mm	0.1 mm	0.1 mm
Tube voltage	22-35 kVp		20-28kVp
Max. tube current	15mA	20-30mA	20-28mA kV / Small 22-24 / 24 25-28 / 28 29-34 / 24 35 / 20
mAs	100mAs		

• describe the method of implementing automatic exposure control (AEC) if provided as part of the system (for example, low level pre-exposure using the image receptor as the AEC detector).

- Most systems measure the compressed breast thickness and use it. kV and target filter are changed to adjust to a lower or higher dose depending on the breast compression thickness.
- To verify AEC operation, tested ACR Phantom to check the value of kVp and mAs.
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4) X-ray Anti-scatter grid

- Genoray = 4:1 91 lines/cm
  Instrumentarium AlphaST = 5:1, 31 lines/cm
- primary transmission: N/A
- Anti-scatter grid provides the benefit of dose reduction. If the grid is not used and the dose is high, the exposure time is increased and the tube generates more heat.

5) Breast compression system

- 18 X 24cm /24x29 Compression Paddle, Polycarbonate material must match the size of the image receptor to prevent pushing the structure out of FOV
- Electric / manual combination method, press the foot switch to proceed (all)
- Fine adjustment by turning the breast compression knob (all)
- Emergency compression release by pressing the compression release switch

7. Summary of Performance Testing

The 2430MCA Digital Flat Panel X-Ray Detector has the similar indications for use, same scintillator material (CsI), and same risk management characteristics compared to the predicate devices. The pixel matrix and pixel pitch size of the subject device are similar but different in comparison with the predicate device due to different detector size. However, the differences do not raise new concerns for the safety and effectiveness of the subject device.

The non-clinical test report and clinical consideration report for each subject device were prepared and submitted to FDA separately to demonstrate the substantial equivalency of the subject device compared to the predicate device. The non-clinical test report contains the sensitometric response, spatial resolution, noise analysis, dynamic range, erasure, fading, repeat exposures, AEC performance for the 2430MCA detector consistent with IEC 62220-1-2.

The MTF and DQE performance for the subject device has been compared with the predicate device. The MTF and DQE represent the ability to visualize object details of a certain size and contrast. 2430MCA has

demonstrated superior MTF and DQE performance in comparison with RSM 1824C , the predicate device, at all spatial frequencies.

To further demonstrate the substantial equivalency of the subject and predicate device, clinical images obtained from the subject device and the predicate device are reviewed by three MQSA qualified US radiologists to render an expert opinion. Both the subject (2430MCA) and the predicate devices (RSM 1824C) have been evaluated and compared by taking sample radiographs of similar age groups and anatomical structures in accordance with the test protocol of screening radiography.

In compliance with CDRH's Guidance for Industry and FDA Staff – Class II Special Controls Guidance Document: Full Field Digital Mammography System, the concurrent review of radiographic images taken from 2430MCA and RSM 1824C confirmed that 2340MCA, the subject device, provide images of equivalent or superior diagnostic capability to the predicate device.

Based on the non-clinical and clinical consideration test and the outcome of a comparative review by an expert for both devices, the sponsor can claim the substantial equivalency between the subject devices and their predicate devices in terms of screening 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 in the submission:

- 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 62220-1-2: Medical electrical equipment - Characteristics of digital X-ray imaging devices - Part 1-2: Determination of the detective quantum efficiency - Detectors used in mammography
- Non-clinical consideration according to FDA Guidance "Guidance for Industry and FDA Staff - Class II Special Controls Guidance Document: Full Field Digital Mammography System"
- "Guidance for the Contents of Premarket Submission for Software Contained in Medical Device".

8. Conclusions:

After a review of plain radiographic images taken with 2430MCA and RSM 1824C, the images reviewed were found to be of acceptable overall clinical image quality for screening mammography. Based on the

clinical and non-clinical consideration for the subject device, Rayence, the sponsor, claims the substantial equivalency between the subject device and the predicate device in terms of screening image quality without new concern for safety and effectiveness.