March 12, 2025

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

Re: K243849
Trade/Device Name: 2430TCA 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: February 11, 2025
Received: February 11, 2025

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 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,

YANNA S. KANG -S

Yanna Kang, Ph.D.
Assistant Director
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DHT8C: Division of Radiological
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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.*

Submission Number *(if known)*

K243849

Device Name

2430TCA with Xmaru W

Indications for Use *(Describe)*

The 2430TCA 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 2430TCA 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.**

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.***

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# 510(k) Summary
# K243849

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:** March 13, 2025

**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, Republic of Korea
**Submitter's Telephone:** +82-31-8015-6459
**Contact person**: Mr. Dong Hyeon Oh / Manager / +82-31-8015-6298

**Official Correspondent:** Dave Kim, MBA (davekim@mtechgroupllc.com)
Mtech Group LLC
**Address:** 7505 Fannin St. Ste 610, Houston, TX 77054
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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:**

**Proposed Device : K243849**

| | Detector(2430TCA) | Software (Xmaru W) |
|---|---|---|
| **Trade/proprietary name** | 2430TCA 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 |
| Regulation Class | Class II | Class II |
| Product Code | MUE | LLZ |

**Predicate Device : K202902**

| | 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 |
| Regulation Class | Class II | Class II |
| Product Code | MUE | LLZ |

## 3. Device Description

2430TCA 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 TFT 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.
2430TCA detector is connected to the viewing station via a LAN cable.

## 4. Indication for use

The 2430TCA 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 2430TCA detector.

## 5. Summary of Design Control Risk management

2430TCA digital X-ray detector is a modification of 2430MCA (K202902).
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.

## 6. 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 (K202902).

### 6.1 Scintillator layer

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

| Scintillator Type | Proposed | Predicate |
|---|---|---|
| CsI (Cesium Iodide) | 2430TCA | 2430MCA (K202902) |

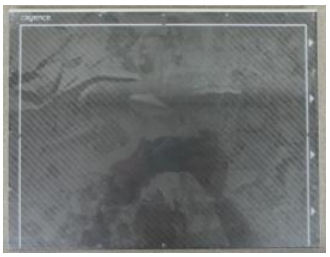
### 6.2 Power source

| | | Proposed 2430TCA | Predicate 2430MCA |
|---|---|---|---|
| Power | Type | Power supply | Power supply |
| | Model name | RP006A | RS1417 |
| | Dimension | 188 X 92 X 41.5 | 188 X 92 X 41.5 |
| | Weight | 0.5 | 0.5 |
| | Rating | Input: 100-240VAC (50/60Hz)<br>Output: 24VDC (Max 1.7A) | Input: 100-240VAC (50/60Hz)<br>Output: 24VDC (Max 1.7A) |

### 6.3 Recommended Generator specifications

| | 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<br>kV / Large<br>22-24 / 80<br>25-28 / 80<br>29-34 / 70<br>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<br>kV / Small<br>22-24 / 24<br>25-28 / 28<br>29-34 / 24<br>35 / 20 |
| mAs | 100mAs | | |

### 6.4 Comparison table

| | Subject device | Predicate device | |
|---|---|---|---|
| **Model** | 2430TCA | 2430MCA | **Similarity** |
| ***Feature*** |  |  | - |
| ***Intended Use*** | The 2430TCA 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 2430TCA detector. | 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. | Same |
| ***Detector Type*** | TFT Photodiode Array | CMOS Photodiode Array | different detector type but it is same indirect conversion method of Radiation image detection |
| ***Scintillator*** | CsI:Tl | CsI:Tl | Same |
| ***Imaging Area*** | 227.3 X 289.0 mm | 231.8 X 304.0 mm | Similar |
| ***Pixel pitch*** | 74 μm | 70 μm (Full resolution)<br>140 μm (2x2 binning) | Similar |
| ***Total Pixel matrix*** | 3072 X 3906 | 3312 X 4344 (Full resolution)<br>1656 X 2172 (2x2 binning) | Similar |
| ***DQE*** | 2.0lp/mm : 57.6<br>5.0 lp/mm : 18.8 | 2.0lp/mm : 57.8<br>5.0 lp/mm : 26.4 | Similar |
| ***MTF*** | 2.0lp/mm : 62.5<br>5.0lp/mm : 25.3 | 2.0lp/mm : 51.5<br>5.0lp/mm : 12.5 | Similar |
| ***A/D conversion*** | 16 bits | 14 bits | Different A/D conversion bit |

| | | | |
|---|---|---|---|
| | | | but this means that the 2430TCA can convert more analog values to digital. |
| ***Dimensions*** | 327.5 X 253.7 X 15mm | 327.5 X 253.7 X 14.2mm | Similar |
| ***Weight*** | 1.9 kg | 2.2 kg | Similar |
| ***Viewer Software (option)*** | Xmaru W | Xmaru W | Same |

## 7. Summary of Performance Testing

2430TCA X-ray detector has the same indications for use, scintillator material (CsI:T1), general specifications, and the same risk analysis characteristics compared to the predicate device, 2430MCA (K202902). The pixel matrix and pixel pitch sizes are different due to different imaging areas. However, the differences do not raise new concerns for the safety and effectiveness of the subject device.

The clinical and non-clinical test reports for the subject device were prepared and submitted to FDA to demonstrate the substantial equivalency of the subject device's performance compared to the predicate device.
Upon review by MQSA-certified radiologists of the plain radiographic images taken with 2430TCA and the 2430MCA, overall, better image quality of the same anatomical position in the separate patients.
The outline of the breasts is clearly visible with the delineation of linear structures featuring margins and microcalcification. Contrast resolution and brightness were better depicted on the subject device with better anatomical structures and artifacts detection. When enlarged on a mammography display, the subject device had less background noise interference than the predicate device. Reviewers found all studies acceptable overall clinical image quality for screening mammography.

In conclusion, both 2430TCA and 2430MCA have demonstrated sufficient image quality to 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 the same analysis method described by IEC 62220-1.

Based on the evaluation of non-clinical considerations, the sponsor can claim the substantial equivalence between the subject device and the predicate device regarding diagnostic image quality.

The manufacturing facility is in conformance with the design control procedure requirements specified in 21 CFR 820.30 and the relevant 21 CFR820 standards, as the records are available for review.

## 8. 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 62220-1-2: 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"
- Content of Premarket Submissions for Management of Cybersecurity in Medical Devices

## 9. Conclusions:

In accordance with the performance outcomes, 2430TCA X-ray detectors demonstrated equivalent or better performance compared to 2430MCA. Therefore, Rayence claims the substantial equivalency between the subject device and the predicate device in terms of diagnostic image quality about safety and effectiveness.