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

October 26, 2020

Re: K202722
Trade/Device Name: 1212FCA
Regulation Number: 21 CFR 892.1680
Regulation Name: Stationary x-ray system
Regulatory Class: Class II
Product Code: MQB
Dated: September 15, 2020
Received: September 17, 2020

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,

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)*
K202722

Device Name

1212FCA

Indications for Use *(Describe)*

1212FCA is indicated for digital imaging solution designed for human anatomy 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.***

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# 510(k) Summary
# K202722

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:** October 15, 2020

**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@mtech-inc.net**)**
**Address:** 7707 Fannin St. Ste 200-V111, 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** **:** 1212FCA
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 :1012WCC
Common Name : Digital Flat Panel X-ray Detector
510(k) Number : K162518
Regulation Number : 21 CFR 892.1680
Regulation Name : Stationary X-ray System
Regulatory Class : Class II
Product Code : MQB

## 2. Device Description

1212FCA is a digital solid state X-ray detector that is based on flat-panel technology. This radiographic image detector and processing unit consists of a scintillator coupled to an IGZO TFT sensor. This device needs to be integrated with a radiographic imaging system. It 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 for a radiographic diagnosis and analysis.
The subject detectors are not wireless, but they are connected to a viewing station by ethernet connection.

## 3. Indication for use

1212FCA is indicated for digital imaging solution designed for human anatomy including head, neck, cervical spine, arm, leg and peripheral (foot, hand, wrist, fingers, etc.).It is intended to replace film or screen based radiographic systems in all general purpose diagnostic procedures. Not to be used for mammography.

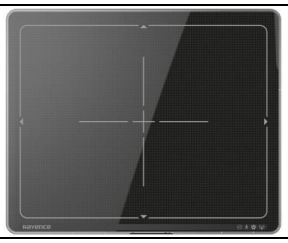
## 4. Summary of Design Control Risk management

1212FCA digital X-ray detector is a modification of 1012WCC (K162518). 1212FCA was developed for the purpose of retrofitting the stationary X-ray system with a film detector. 1212FCA is slightly larger than 1012WCC (K162518).
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:

1212FCA detector described in this 510(k) have the same indications for use and similar technical characteristics as its predicate devices, 1012WCC (K162518).

## 5.1 Comparison table

| **Characteristic** | | **Proposed Device** | **Predicate Device** | |
|---|---|---|---|---|
| ***Manufacturer*** | | **Rayence Co.,Ltd.** | **Rayence Co.,Ltd.** | |
| ***Product Name*** | | 1212FCA | 1012WCC | |
| ***Feature*** | |  |  | |
| ***510(k) number*** | | K202722 | K162518 | |
| ***Intended Use*** | | 1212FCA is indicated for digital imaging solution designed for human anatomy 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. | 1012WCC and 1012 WGC Digital Flat Panel X-Ray Detector is indicated for digital imaging solution designed for human anatomy 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. | Similar |
| ***Detector Type*** | | IGZO TFT + PIN type photodiode | Amorphous Silicon, TFT | Similar |
| ***Scintillator*** | | CsI:Tl | CsI:Tl | Same |
| ***Imaging Area*** | | 12 x 12 inches | 10 x 12 inches | Similar |
| ***Pixel matrix*** | | 1536 X 1536 (Full resolution)<br>768 X 768 (2x2 binning) | 2304 X 1792 | Similar |
| ***Pixel pitch*** | | 194 μm (Full resolution) / 388 μm (2x2 binning) | 127 μm | Similar |
| ***A/D conversion*** | | 14 / 16 bit | 14 / 16bit | Same |
| ***Frame rate*** | | 18 (Full resolution) / 36 (2x2 binning) | - | Not known |
| ***MTF*** | 0.1 lp/mm | 0.527 | 0.488 | |
| | 1 lp/mm | 0.327 | 0.283 | |
| | 2 lp/mm | 0.210 | 0.181 | |
| | 2.5 lp/mm | 0.136 | 0.117 | |
| ***DQE (0)*** | | 0.778 | 0.756 | |
| ***Preview time*** | | ≤2 seconds | ≤2 seconds | Same |

| | | | |
|---|---|---|---|
| ***Data output*** | RAW<br>*The RAW files are convertible into DICOM 3.0 by console S/W | RAW<br>*The RAW files are convertible into DICOM 3.0 by console S/W | Same |
| ***Dimensions*** | 334.0 x 326.0 x 49.9 mm | 328 X 268 X 15 mm | Similar |
| ***Weight*** | 3.4 kg | 3.5 kg (incl. battery) | Similar |

### 5.2 Scintillator layer

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

| | **Proposed** | **Predicate** |
|---|---|---|
| CsI (Cesium Iodide) | 1212FCA | 1012WCC |

### 5.3 Power source

| | | **Proposed**<br>1212FCA | **Predicate**<br>1012WCC |
|---|---|---|---|
| Power | Type | Power adapter | Power supply |
| | Model name | AHM85PS24 | RP003A |
| | Dimension | 150 X 64 X 37<br>(cable length: 900 mm) | 188 X 92 X 41.5 |
| | Weight | 0.5 | 0.5 |
| | Rating | Input: 100-240 Vac, 1.0 A, 50/60 Hz<br>Output: 24VDC (Max 3.54A) | Input: 100-240VAC (50/60Hz)<br>Output: 24VDC (Max 1.7A) |

### 5.4 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 | | |

## 6. Summary of Performance Testing

1212FCA Digital Flat Panel X-Ray Detector has the same indications for use, the same scintillator material (CsI:Tl ), the same generator specifications and the same risk analysis characteristics compared to 1012WCC, the predicate devices (K162518). 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 was prepared and submitted to FDA to demonstrate the substantial equivalency of the subject device performance compared to the predicate device. The non-clinical test report contains the MTF, DQE and NPS performance test comparison between the subject device (1212FCA), and the predicate device (1012WCC), 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. 1212FCA demonstrated equivalent or better performance in terms of MTF and DQE as well as NPS compared to 1012WCC, 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 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 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:

Based on the non-clinical consideration performance outcomes, Rayence, the sponsor, claims the substantial equivalency between the subject device and the predicate device in terms of diagnostic image quality with no new concern for safety and effectiveness.