K141563
p. 1 of 8



## 510(k) Summary

JUL 16 2014

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:** June 11, 2014

**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 / Manager / +82-31-8015-6459 |
| **Official Correspondent:** | Dave Kim (davekim@mtech-inc.net) |
| **(U.S. Designated agent)** | |
| **Address:** | 8310 Buffalo Speedway, Houston, TX 77025 |
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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:**

| | |
|---|---|
| **Trade/proprietary name:** | 1417WGC |
| **Common Name:** | Digital Flat Panel X-ray Detector |
| **Classification Name :** | 21CFR892.1680 / Stationary x-ray system |
| **Product Code:** | MQB |

**Predicate Device :**

| | |
|---|---|
| Manufacturer | : Rayence Co., Ltd. |
| Device | : 1417WGA |
| 510(k) Number | : K131114 (Decision Date – September 17, 2013) |

**Device Description :**

1417WGC is a wired/wireless digital solid state X-ray detector that is based on flat-panel technology. The wireless LAN(IEEE 802.11a/g/n) communication signals images captured to the system and improves the user operability through high-speed processing. This radiographic image detector and processing unit consists of a scintillator coupled to an a-Si 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 (not part of this 510k submission) for a radiographic diagnosis and analysis.

**Indication for use** :

1417WGC 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.

## 1. Summary of Design Control Risk management

The 1417WGC digital X-ray detector is a modification of 1417WGA (K131114). The new device is designed with a thinner and lighter body compared to its predecessor, 1417WGA. The battery of 1417WGA was attached on the back of the device but the newly designed 1417WGC device has its battery inserted inside the new device.

In addition, a dedicated power supply (model name: RP003A) for 1417WGC is developed and added to its component list. (Optional user selection).

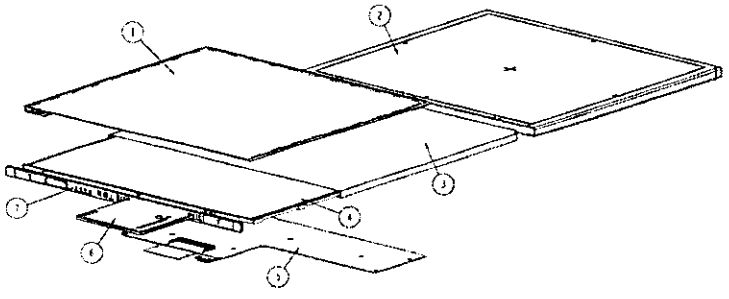
The risks and the hazardous impact of the device modification were analyzed with FMEA method. The specific risk control and protective measures to mitigate the risks from the modification were reviewed and implemented in the new product design phase. The overall assessment concluded that all risks and hazardous conditions identified arising from the design change were successfully mitigated and accepted.

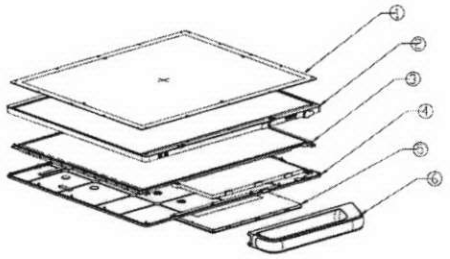
## 2. Summary of the technological characteristics of the device compared to the predicate device:

The 1417WGC SSXI detector described in this 510(k) has the same indications for use and technical characteristics as its predicate device, 1417WGA flat panel detector, of Rayence Co., Ltd.

2.1 Detector

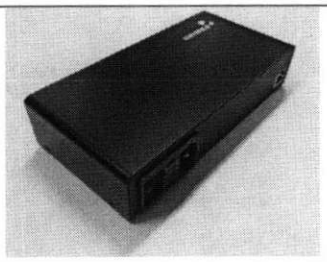
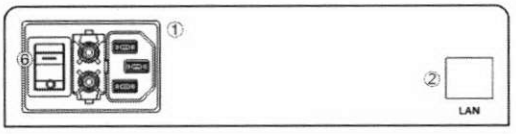
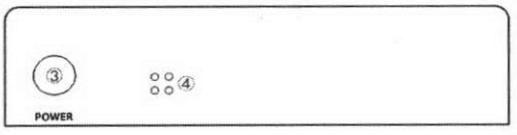
The mechanical design for each device is different as following.

| |
|---|
| 1417WGC<br>Dimensions- 460 X 384 X 15.4 mm / Weight- 3.1 kg |
|  <br>1. Carbon Plate<br>2. Carbon case<br>3. PC Sheet ass'y<br>4. Middle block ass'y<br>5. Main B'd<br>6. Cap ass'y |
| 1417WGA<br>Dimensions- 460 x 417 x 15.9 mm / Weight- 3.9 kg |

| | |
|---|---|
|  | 1. Carbon Plate<br>2. Front cover<br>3. Middle block & Panel<br>4. Rear Cover<br>5. Battery Pack<br>6. Handle |

2.2 Power supply

1417WGC requires power supply (Model Name: RP003A)

| | 1417WGC | 1417WGA |
|---|---|---|
| Model Name | RP003A | The power supply unit is not provided from Rayence. |
| |  <br>  <br><br>  <br><br>① Power plug connector: Connect with AC power supply cord<br>② LAN connector : Ethernet port for transmitting the image/command between detector and PC<br>③ Link cable connector: Power connector for detector operating<br>④ LED indicator: Four LEDs to display the status<br>※Changeable part: Fuse T3.15 AL 250V | |
| Manufacturer | Rayence Co., Ltd. | |

| | | |
|---|---|---|
| Dimension | 188 X 92 X 41.5 mm | |
| Weight | 0.46 kg | |
| Power requirements | Input rate : 100 ~ 240VAC (50/60Hz)<br>Output : Typ. 24VDC (Max 1.6A) | *** Use CE or UL approved product**<br>Voltage: Min 18V, Max 24V<br>Current: Min 1.9A, Max - |

The 1417WGC flat panel detector is equipped with a dedicated power supply (Model Name: RP003A). The electromagnetic compatibility test for the new device with the power supply has been conducted and the test report is included in this submission. The risk factors associated with the power supply such as power overload and overheating have been assessed and control measures to mitigate risks are discussed.

2.3 A/D conversion (analog-to-digital conversion)

The detector displays an image by digitizing and recording DN value of the analog electrical signal measured. The predicate device used 14 bit series to represent 16,384 values on the gray scale whereas the newly improved subject device is capable of processing both 14 and 16 bit (65,536 gray scale values) series based on the user needs and market requirements.

| **Characteristic** | **Proposed**<br>**Rayence Co.,Ltd.**<br>***1417WGC*** | **Predicate**<br>**Rayence Co.,Ltd.**<br>***1417WGA*** |
|---|---|---|
| ***A/D conversion*** | 14 / 16 bit | 14 bit |

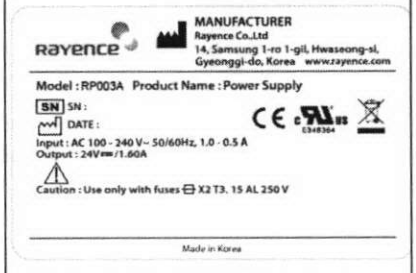
2.4 Recommended Generator Specification

| 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 |

Note: To our best knowledge, the 1417WGC detector is compatible with the X-ray generators with the specifications described above. For any questions regarding the compatibility issue for other generators which are not listed above, please contact Rayence representative.

## 3. Proposed Labeling- Changes in comparison to the predicate device

| Item | Difference | 1417WGC | 1417WGA |
|---|---|---|---|
| Device Label | Detector |  |  |
| | Power Supply |   | - |
| Manual | Indications for Use | 1417WGC 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 | 1417WGA 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. |

| | | | |
|---|---|---|---|
| | | procedures. Not to be used for mammography. | |
| | Product Specification | (page 25)<br>Pixel matrix: 3328 x 2816<br>Pixel area (active): 415 x 350 mm<br>Dimensions : 460 x 384 x 15.4 mm<br>Weight: 3.1 kg | (page 25)<br>Pixel matrix: 3328 x 2816<br>Pixel area (active): 415 x 350 mm<br>Dimensions : 460 x 417 x 15.9 mm<br>Weight: 3.9 kg |
| Wireless Spec | Standard | 802.11a/g/n compliance | 802.11a/g/n compliance |
| | Peak Rate | 300Mbps | 300Mbps |
| | Frequency | 2.4 GHz / 5 GHz | 2.4 GHz / 5 GHz |
| | Bandwidth | 20MHz/40MHz | 20MHz/40MHz |
| | MIMO | 2x2 | 2x2 |

## 4. Summary of Performance Testing

The 1417WGC flat panel detector is a modified version of 1417WGA (K131114), FDA cleared predicate device from Rayence. Indications for use, material, form factor, performance, and safety characteristics between 1417WGC and 1417WGA are identical.

The non-clinical test report and clinical consideration report were prepared and submitted to FDA separately to demonstrate the substantial equivalency between two similar detectors. The non-clinical test report contains the MTF, DQE and NPS test results of 1417WGC and 1417WGA by using the identical test equipment and same analysis method described by IEC 62220-1. The comparison of the MTF for 1417WGC and 1417WGA detector demonstrated that the MTF of the 1417WGA detector performed almost same with 1417WGC. Therefore, the overall resolution performance and sharpness of 1417WGC is almost same with 1417WGA. The DQE represents the ability to visualize object details of a certain size and contrast. 1417WGC demonstrated higher DQE performance than 1417WGA at various spatial frequencies and provides almost same Signal-to Noise Ratio (SNR) transfer from the input to the output of a detector as a function of frequency. At the lowest spatial frequency, 1417WGC has a DQE of 49% and that of 1417WGA is 46%. 1417WGC also exhibited NPS which has almost same performance with 1417WGA. Therefore, the image quality of 1417WGC is found to be substantially equivalent to 1417WGA at the same patient exposure.

To further demonstrate the substantial equivalency of two devices, clinical images are taken from both devices and reviewed by a licensed US radiologist to render an expert opinion. Both the test subject (1417WGC) and control group (1417WGA) are evaluated and compared by taking sample radiographs of similar age groups and anatomical structures in accordance with the test protocol of diagnostic radiography evaluation procedure.

Based on the non-clinical and clinical consideration test and the outcome of a comparative review by an expert for both devices, we can claim the substantial equivalency between 1417WGC and its predicate device, 1417WGA in terms of image quality.

After comparing a broad review of plain radiographic images taken with the 1417WGC and the 1417WGA, the images obtained with the 1417WGC are comparable or superior to the same view obtained from a similar patient with the 1417WGA. In general, both the spatial resolution and soft tissue contrast are superior using the 1417WGC. Specifically, the soft tissues on extremity films were seen with better clarity. There is no difficulty in evaluating a wide range of anatomic structures necessary to provide a correct conclusion.

The manufacturing facility is in conformance with the design control procedure requirements and the relevant EPRC standards as specified in 21 CFR 802.30 and the records are available for review.

## 5. Summary for any testing in the submission:

Electrical, mechanical, environmental safety and performance testing according to standard IEC 60601-1: 2005 + CORR.1(2006) + CORR(2007) (Medical electrical equipment Part 1:General requirements for basic safety and essential performance) was performed, and EMC testing were conducted in accordance with standard IEC 60601-1-2:2007.

Non-clinical & Clinical considerations according to FDA Guidance "Guidance for the Submissions of 510(k)'s for Solid State X-ray Imaging Devices" was performed.

All test results were satisfactory.

## 6. Conclusions:

In accordance with the Federal Food, Drug and Cosmetic Act, 21 CFR Part 807 and based on the information provided in this premarket notification Rayence Co., Ltd. concludes that 1417WGC is safe and effective and substantially equivalent in comparison with 1417WGA, the predicate device as described herein.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

July 16, 2014

Rayence Co., Ltd.
% Mr. Dave Kim
Medical Device Regulatory Affairs
8310 Buffalo Speedway
HOUSTON TX 77025

Re: K141563
Trade/Device Name: Solid State X-ray Imaging Device, Digital Flat Panel X-ray Detector, 1417wgc
Regulation Number: 21 CFR 892.1680
Regulation Name: Stationary x-ray system
Regulatory Class: II
Product Code: MQB
Dated: June 12, 2014
Received: June 16, 2014

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. 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.

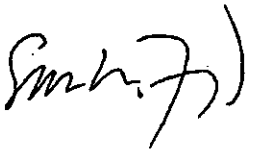
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,



for

Janine M. Morris
Director
Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
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: December 31, 2013
*See PRA Statement on last page.*

510(k) Number *(if known)*
K141563

Device Name
1417WGC Digital Flat Panel X-Ray Detector

Indications for Use *(Describe)*

1417WGC 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 807 Subpart C)

**PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.**

**FOR FDA USE ONLY**

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

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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