



Food and Drug Administration
10903 New Hampshire Avenue
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Rayence Co., Ltd.
% Mr. Dave Kim
Medical Device Regulatory Affairs
Mtech Group
8310 Buffalo Speedway
HOUSTON TX 77025

October 6, 2016

Re: K162519
Trade/Device Name: 1717WCC / 1717WGC
Regulation Number: 21 CFR 892.1680
Regulation Name: Stationary x-ray system
Regulatory Class: II
Product Code: MQB
Dated: September 1, 2016
Received: September 9, 2016

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,

A handwritten signature in black ink that reads "Robert Ochs". The signature is written in a cursive style. Behind the signature, there is a faint, light blue watermark of the letters "FDA".

Robert Ochs, Ph.D.
Director
Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known)

K162519

Device Name

1717WCC

1717WGC

Indications for Use (Describe)

1717WCC and 1717WGC Digital Flat Panel X-Ray Detectors are 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.

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1. 510(k) Summary

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 3, 2016

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)
(U.S. Designated agent)
Address: 8310 Buffalo Speedway, Houston, TX 77025
Telephone: +713-467-2607
Fax: +713-583-8988

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: 1717WCC / 1717WGC
Common Name: Digital Flat Panel X-ray Detector
Classification Name : 21CFR892.1680 / Stationary x-ray system
Product Code: 90 MQB

Predicate Device :

Manufacturer : Rayence Co., Ltd.
Device : 1717SCN / 1717SGN
510(k) Number : K150150
Classification Name : 21CFR892.1680 / Stationary x-ray system
Product Code: MQB

2. Device Description

1717WCC / 1717WGC 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/ac) 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 a separate console SW program (K160579 / Xmaru View V1 and Xmaru PACS/ Rayence Co.,Ltd.) for a diagnostic analysis.

3. Indication for use

1717WCC and 1717WGC Digital Flat Panel X-Ray Detectors are 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

The 1717WCC / 1717WGC digital X-ray detector is a modification of 1717SCN / 1717SGN (K150150). It was developed for the purpose of portable imaging. 1717WCC / 1717WGC is slightly thinner and lighter than 1717SCN / 1717SGN.

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:

1717WCC and 1717WGC detector described in this 510(k) have the same indications for use and similar technical characteristics as the predicate devices, 1717SGN and 1717SCN.

5.1 Comparison table

| Characteristic | Proposed Rayence Co.,Ltd. 1717WCC / 1717WGC | | Predicate Rayence Co.,Ltd. 1717SCN / 1717SGN | |
|----------------------------------|--|-------------------------------------|---|-------------------------------------|
| Feature |  | |  | |
| 510(k) number | - | | K150150 | |
| Intended Use | 1717WCC and 1717WGC Digital Flat Panel X-Ray Detector are 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. | | 1717SGN and 1717SCN 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. | |
| Detector Type | Amorphous Silicon, TFT | | Amorphous Silicon, TFT | |
| Scintillator | 1717WCC | CsI:Tl | 1717SCN | CsI:Tl |
| | 1717WGC | Gd ₂ O ₂ S:Tb | 1717SGN | Gd ₂ O ₂ S:Tb |
| Imaging Area | 17 x 17 inches | | 17 x 17 inches | |
| Pixel matrix | 127 : 3328 X 3328 139, 140 : 3072 X 3072 | | 3072 x 3072 | |
| Pixel pitch | 127, 139, 140 μm | | 127 μm | |
| Resolution | 3.9 lp/mm | | 3.9 lp/mm | |
| A/D conversion | 14 / 16 bit | | 14 / 16 bit | |
| Preview time | ≤2 | | ≤2 | |
| Data output | RAW *The RAW files are convertible into DICOM 3.0 by console S/W | | RAW *The RAW files are convertible into DICOM 3.0 by console S/W | |
| Dimensions | 460 × 460 × 15 mm | | 460 × 460 × 15.5 mm | |
| Weight | 3.5 kg (incl. battery) | | 4 kg | |
| Application | General Radiology system or Wireless/Wired portable system Available with upright stand, table, universal stand. | | General Radiology system or Portable system Available with upright stand, table, universal stand. | |
| Added Optional Components | Battery & Battery Charger Interface Box IrDA module | | - | |

5.2 Scintillator layer

1717WCC / 1717WGC has the same Hardware, Software and components. The type of a *scintillator* layer is different. (* *scintillator* : a phosphor that produces scintillations) as described below.

| | Proposed | Predicate |
|--|----------|-----------|
| CsI (Cesium Iodide) | 1717WCC | 1717SCN |
| Gd ₂ O ₂ S:Tb (Gadolinium Oxysulfide) | 1717WGC | 1717SGN |

5.3 Added Optional Components (Comparison with Predicate device)

| Components | Description |
|--|---|
| <p>Battery & Battery Charger</p>  | Sources of electricity. |
| <p>Mobile Battery Charger</p>  | |
| <p>Interface Box</p>  | <ol style="list-style-type: none"> 1) Connector to synchronize the detector and its generator. 2) Data transfer and battery charge while the detector is in use (Connect between the detector and Interface Box), Up to three detectors can be connected. 3) Transmitting an image/command between the detector and PC. 4) Wireless AP. |
| <p>IrDA module</p>  | Sharing function for PC and the detector. |

5.4 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 | | |



CAUTION

- To our best knowledge, the detector is compatible with the X-ray generators with the specifications described above. If you have questions regarding the compatibility issue for other generators which are not listed above, please contact your Rayence representative.

6. Summary of Performance Testing

1717WCC and 1717WGC Digital Flat Panel X-Ray Detector have the same indications for use, material, form factor, performance, and safety characteristics compared to the predicate devices, 1717SCN and 1717SGN, respectively.

The non-clinical test and clinical consideration test for each subject device were performed to demonstrate the substantial equivalency of the subject devices compared to each respective predicate device. The non-clinical test report contains the MTF, DQE and NPS test results of 1717WCC and 1717WGC by using the identical test equipment and same analysis method described by IEC 62220-1.

The comparative result of the MTF and DQE test for 1717WCC and 1717WGC detector with respect to each respective predicate demonstrated that the MTF and DQE of the both subject devices performed better

compared with each respective predicate device. The MTF and DQE represents the ability to visualize object details of a certain size and contrast. 1717WCC has higher MTF and DQE performance at high spatial frequencies, especially from 2 lp/mm to 3.5 lp/mm. The comparison of the MTF and DQE for 1717WGC detector demonstrated that the performed almost same with 1717SGN.

| Spatial Frequency | MTF Value | | | |
|-------------------|-------------|---------|-------------|---------|
| | 1717WCC_127 | 1717SCN | 1717WGC_127 | 1717SGN |
| 1.0 lp/mm | 0.539 | 0.566 | 0.557 | 0.574 |
| 2.0 lp/mm | 0.262 | 0.251 | 0.247 | 0.269 |
| 3.0 lp/mm | 0.147 | 0.123 | 0.106 | 0.123 |
| 3.5 lp/mm | 0.105 | 0.086 | 0.067 | 0.082 |
| 3.93 lp/mm | 0.086 | 0.080 | 0.046 | 0.076 |

| Spatial Frequency | MTF Value | | | |
|-------------------|-------------|---------|-------------|---------|
| | 1717WCC_139 | 1717SCN | 1717WGC_139 | 1717SGN |
| 1.0 lp/mm | 0.537 | 0.566 | 0.556 | 0.574 |
| 2.0 lp/mm | 0.269 | 0.251 | 0.260 | 0.269 |
| 3.0 lp/mm | 0.145 | 0.123 | 0.123 | 0.123 |
| 3.5 lp/mm | 0.110 | 0.086 | 0.084 | 0.082 |
| 3.59 lp/mm | 0.104 | 0.080 | 0.078 | 0.076 |

| Spatial Frequency | MTF Value | | | |
|-------------------|-------------|---------|-------------|---------|
| | 1717WCC_140 | 1717SCN | 1717WGC_140 | 1717SGN |
| 1.0 lp/mm | 0.580 | 0.566 | 0.556 | 0.574 |
| 2.0 lp/mm | 0.269 | 0.251 | 0.260 | 0.269 |
| 3.0 lp/mm | 0.139 | 0.123 | 0.123 | 0.123 |
| 3.5 lp/mm | 0.098 | 0.086 | 0.084 | 0.082 |
| 3.57 lp/mm | 0.093 | 0.081 | 0.078 | 0.076 |

| | 1717WCC_127 | 1717SCN | 1717WGC_127 | 1717SGN |
|--------|-------------|---------|-------------|---------|
| DQE(0) | 0.71 | 0.700 | 0.444 | 0.420 |
| | 1717WCC_139 | 1717SCN | 1717WGC_139 | 1717SGN |
| DQE(0) | 0.705 | 0.700 | 0.446 | 0.420 |

| | 1717WCC_140 | 1717SCN | 1717WGC_140 | 1717SGN |
|--------|-------------|---------|-------------|---------|
| DQE(0) | 0.775 | 0.700 | 0.440 | 0.420 |

This information will be included as a part of proposed labeling documentation for the end user.

To further demonstrate the substantial equivalency of two devices, clinical images are taken from both subject devices and reviewed by a licensed US radiologist to render an expert opinion. Both the test subject (1717WCC and 1717WGC) and the predicate devices (1717WGC and 1717SGN) have been 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.

After a broad review of plain radiographic images taken with the 1717WCC and the 1717WGC, the images obtained with the 1717WCC and 1717WGC are superior to the same view obtained from a similar patient with the predicate devices, 1717WGC and 1717SGN. In general, both the spatial and soft tissue contrast resolution are superior using the 1717WCC an 1717WGC. Specifically, the soft tissues on extremity films were seen with better clarity. There is little difficulty in evaluating a wide range of anatomic structures necessary to provide a correct conclusion.

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 diagnostic image quality.

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.

7. Summary for any testing in the submission:

Electrical, mechanical, environmental safety and performance testing according to standard IEC 60601-1:2005 (3rd Edition) + CORR. 1:2006 + CORR. 2:2007 + A1:2012 (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.

8. Summary for risk management activities in the submission:

| Added function | | Risk factor | Discussion |
|----------------|------------------------------------|----------------------------|--|
| 1 | Essential performance (Image size) | -. Pixel Pitch 127/139/140 | Pixel Pitch of 127 and 139 are added to the existing 140 type. Therefore, the total pixel matrix, total pixel area, effective and pixel matrix have been changed. The SSXI Nonclinical/Clinical test of the new detector determined that the image quality of the new detector to be substantially equivalent to the predicate device. The revised RM table; Att 3-1 and Att 302 include the following risk: Operational hazard (Incorrect image data) hazard ID (HI-601-1-4.3) which is highlighted in yellow. |

| | | | |
|---|----------|-------------------|---|
| 2 | Wireless | - Battery | <p>The risk related to a wireless product that uses a battery has been identified and mitigated according to IEC 60601-1, IEC62366 test, and SW validation.</p> <p>The revised RM table; Att3-1 and Att 3-2 include the following risk: Operation hazard (Use error)-Incorrect replacement, Hazard ID (HI-601-1-7.3.3) and Operation hazard-Batter connection, Hazard ID (HI-601-1-15.4.3.2) Att3-3 SW validation also includes HZ 0017-power instability caused by low battery power which is highlighted in yellow.</p> |
| | | - Wireless signal | <p>SW validation also identified the following risk and risk management activities regarding the wireless signal; (HZ 0017-power instability caused by low battery power. (HZ 0019)-Misdiagnosis Not possible to check the data validity of all data packets, including CRC value, based on the IrDA communication transmission in the PC and the detector /HZ 0020)-Misdiagnosis Image not transmitted to the User PC due to the network transmission failure. Check the connection between the detector and the User-PC</p> |

9. 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, it is the sponsor’s opinion that 1717WCC and 1717WGC is substantially equivalent in comparison with 1717SCN and 1717SGN, the predicate device as described herein.