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: March 7, 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)	
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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:	1717G
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	: 1717SGC
510(k) Number	: K122182 (Decision Date – AUG. 16. 2012)

Device Description :

1717G 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 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 :

1717G 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 1717G digital X-ray detector is a modification of 1717SGC (K122182). 1717G was developed for the purpose of retrofitting the stationary X-ray system with a film detector. 1717G is slightly larger and heavier than 1717 SGC, the predecessor.

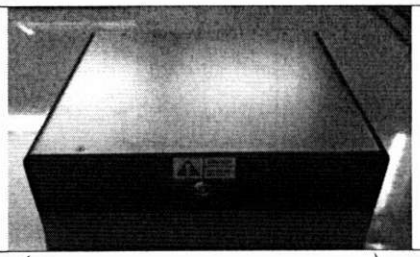
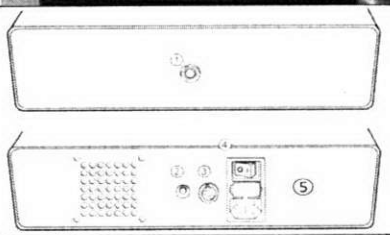
The risks and the hazardous impact of the device modification were analyzed with FMEA method. The specific risk control and protective measures to mitigate the risks from the modification were reviewed and implemented in the new product design phase. The overall assessment concluded that all risks and 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 1717G SSXI detector described in this 510(k) has the same indications for use and similar technical characteristics as its predicate device, 1717SGC flat panel detector, of Rayence Co., Ltd.

The same hardware is used for 1717G and 1717SGC, and the hardware is eivided into the main board, Gate board and ROIC board.

1717G requires power supply (Model Name: RP002A)

<table>
<tr><td></td><td>1717G</td><td>1717SGC</td></tr>
<tr><td>Model Name</td><td>RP002A</td><td rowspan="5">The power supply unit is not provided from Rayence.</td></tr>
<tr><td>Description</td><td>



<table>
<tr><th>No</th><th>Description</th></tr>
<tr><td>①</td><td>Power connector for detector operating
⎓ Direct current</td></tr>
<tr><td>②</td><td>Light up at 5V operating in power supply</td></tr>
<tr><td>③</td><td>110V / 220V select switch – 110V or 220V select (Within 100-120V, 220-240V range)</td></tr>
<tr><td>④</td><td>Input Power | on / ○ Power off by main power switch</td></tr>
<tr><td>⑤</td><td>Connect with AC power supply cord
⎓ Direct current
⏚ Protective Earth (Ground)</td></tr>
</table>
</td></tr>
<tr><td>Manufacturer</td><td>Rayence Co., Ltd.</td></tr>
<tr><td>Dimension</td><td>290 x 245 x 68 mm</td></tr>
<tr><td>Weight</td><td>4 kg</td></tr>
</table>

<table>
<tr>
<td>Power requirements</td>
<td>100-120/220-240 V~, 50/60 Hz, 50 VA
The main power fuse is a 3.15A, 250V~ Type T fuse
<table>
<tr><th>Supply power</th><th>Output Current</th></tr>
<tr><td>DC5.5V</td><td>0.5A</td></tr>
<tr><td>DC5.5V</td><td>0.1A</td></tr>
<tr><td>DC12V</td><td>2A</td></tr>
<tr><td>DC24V</td><td>8A</td></tr>
<tr><td>DC-8V</td><td>0.01A</td></tr>
<tr><td>AC100Vrms(400Hz)</td><td>0.25A</td></tr>
</table>
</td>
<td>* Use CE or UL approved product
<table>
<tr><th></th><th>Min</th><th>Max</th></tr>
<tr><td>Voltage</td><td>18V</td><td>24V</td></tr>
<tr><td>Current</td><td>1.9A</td><td>-</td></tr>
</table>
</td>
</tr>
</table>

The 1717G flat panel detector is equipped with a dedicated power supply (Model Name: RP002A). 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.

3. Summary of Performance Testing

The 1717G flat panel detector is a modified version of 1717SGC (K122182), FDA cleared predicate device from Rayence. Indications for use, material, form factor, performance, and safety characteristics between 1717G and 1717SGC 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 1717G and 1717SGC by using the identical test equipment and same analysis method described by IEC 62220-1. The comparison of the MTF for 1717G and 1717SGC detector demonstrated that the MTF of the 1717SGC detector performed almost same with 1717G. Therefore, the overall resolution performance and sharpness of 1717G is almost same with 1717SGC. The DQE represents the ability to visualize object details of a certain size and contrast. 1717G demonstrated higher DQE performance than 1717SGC 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, 1717G has a DQE of 46% and that of 1717SGC is 45%. 1717G also exhibited NPS which has almost same performance with 1717SGC. Therefore, the image quality of 1717G is found to be substantially equivalent to 1717SGC 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 (1717G) and control group (1717SGC) 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 1717G and its predicate device, 1717SGC in terms of image quality.

After comparing a broad review of plain radiographic images taken with the 1717G and the 1717SGC, the images obtained with the 1717G are comparable or superior to the same view obtained from a similar patient with the 1717SGC. In general, both the spatial resolution and soft tissue contrast are superior using the 1717G. 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.

4. 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.

5. 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 1717G is safe and effective and substantially equivalent in comparison with 1717SGC, 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

April 11, 2014

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

Re: K140646
Trade/Device Name: Digital Flat Panel X-ray Detector / 1717G, Xmaru1717G
Regulation Number: 21 CFR 892.1680
Regulation Name: Stationary x-ray system
Regulatory Class: II
Product Code: MQB
Dated: March 7, 2014
Received: March 13, 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.

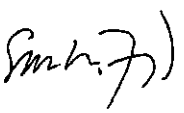
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further 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 Small Manufacturers, International and Consumer Assistance 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" (21CFR 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 Small Manufacturers, International and Consumer Assistance 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)*

K140646

Device Name
1717G Digital Flat Panel X-Ray Detector

Indications for Use *(Describe)*

1717G 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)*

Richard D. O'Hara