DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

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

October 6, 2016

Re: K162518
Trade/Device Name: 1012WCC / 1012WGC
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,

Robert Ochs, Ph.D.
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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*

K162518

Device Name

1012WCC
1012WGC

Indications for Use *(Describe)*

1012WCC and 1012WGC Digital Flat Panel X-Ray Detector are indicated for digital imaging solution designed for human anatomy including head, neck, cervical spine, arm, leg and peripheral (foot, hand, wrist, fingers, etc.). They are 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.

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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 6, 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
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(U.S. Designated agent)	
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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:	1012WCC / 1012WGC
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 :	1012WCA
510(k) Number :	K123345
Common Name:	Digital Flat Panel X-ray Detector
Classification Name :	21CFR892.1680 / Stationary x-ray system
Product Code:	MQB

Reference Device :

Manufacturer :	Rayence Co., Ltd.
Device :	1210SGA
510(k) Number :	K113630
Common Name:	Digital Flat Panel X-ray Detector
Classification Name :	21CFR892.1680 / Stationary x-ray system
Product Code:	MQB

2. Device Description

1012WCC / 1012WGC 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 a DICOM compatible image file by a separate console SW program (K160579 / Xmaru View V1 and Xmaru PACS/ Rayence Co.,Ltd.) for a diagnostic analysis.

3. Indication for use

1012WCC and 1012WGC 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.

4. Summary of Design Control Risk management

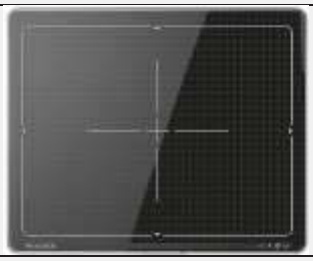
The 1012WCC / 1012WGC digital X-ray detector is a modification of 1012WCA(K123345), the predicate device which was developed for the purpose of portable imaging. 1012WCC / 1012WGC is slightly thinner, smaller and lighter than 1012WCA.

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:

1012WCC and 1012WGC detector described in this 510(k) has the same indications for use and similar technical characteristics as its predicate device, 1012WCA.

5.1 Comparison table

Characteristic	Proposed Rayence Co.,Ltd. 1012WCC / 1012WGC	Predicate Rayence Co.,Ltd. 1012WCA
Feature		
510(k) number	-	K123345
Intended Use	1012WCC and 1012WGC Digital Flat Panel X-Ray Detector are indicated for digital imaging solution designed for human anatomy including head, neck, cervical spine, arm, leg and peripheral (foot, hand, wrist, fingers, etc.). They are 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.	1012WCA 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.
Detector Type	Amorphous Silicon, TFT	Amorphous Silicon, TFT
Scintillator	1012WCC: CsI:Tl 1012WGC: Gd_2O_2S:Tb	CsI:Tl
Imaging Area	10 x 12 inches	11 x 13 inches
Pixel matrix	2304 X 1792	2560 X 2080
Pixel pitch	127 μm	127 μm
Resolution	3.9 lp/mm	3.9 lp/mm
A/D conversion	14 / 16 bit	14 / 16 bit
Preview time	≤2	≤3
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	328 X 268 X 15 mm	395 x 337 x 18 mm
Weight	3.5 kg (incl. battery)	3.15 kg
Application	Wireless/Wired portable system Available with upright stand, table, universal	Wireless portable system Available with upright stand, table, universal

	stand.	stand
Added Optional Components	Battery & Battery Charger Interface Box IrDA module	- Battery & Battery Charger Interface Box

5.2 Scintillator layer

1012WCC and 1012WGC have the same hardware, software and components. The type of a scintillator layer is different. (* scintillator : a phosphor that produces scintillations)

	Proposed	Predicate	Reference
CsI (Cesium Iodide)	1012WCC	1012WCA	
Gd_2O_2S:Tb (Gadolinium Oxysulfide)	1012WGC		1210SGA

5.3 Added Optional Components (Comparison with Predicate device)

Components	Description
Battery & Battery Charger 	Sources of electricity.
Mobile Battery Charger 	
Interface Box 	1) Connector to synchronize the detector and the 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.
IrDA module 	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

1012WCC and 1012WGC Digital Flat Panel X-Ray Detectors have the same indications for use, material, form factor, performance, and safety characteristics compared to the predicate devices, 1012WCA.

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 the predicate device. The non-clinical test report contains the MTF, DQE and NPS test results of 1012WCC and 1012WGC by using the identical test equipment and same analysis method described by IEC 62220-1.

The comparative result of the DQE test for 1012WCC detector with respect to the predicate device demonstrated that the DQE of the both subject devcies performed better compared with the predicate device. The DQE represents the ability to visualize object details of a certain size and contrast. 1012WCC has higher DQE performance at high spartial frequencies, especially from 2.5 lp/mm to 4 lp/mm, compared with 1012WCA. The comparison of the MTF and DQE for 1012WGC detector

demonstrated that the MTF and DQE performance results for the subject device were almost same as those of 1210SGA (K113630), the reference device.

Spatial Frequency	*MTF Value*	
	1012WCC	*1012WCA*
1.0 lp/mm	*0.560*	*0.575*
2.0 lp/mm	*0.259*	*0.278*
3.0 lp/mm	*0.143*	*0.143*
3.5 lp/mm	*0.108*	*0.101*
3.93 lp/mm	*0.086*	*0.074*
Spatial Frequency	*MTF Value*	
	1012WGC	*1210SGA*
1.0 lp/mm	*0.588*	*0.585*
2.0 lp/mm	*0.275*	*0.264*
3.0 lp/mm	*0.131*	*0.119*
3.5 lp/mm	*0.087*	*0.076*
3.93 lp/mm	*0.062*	*0.053*

	1012WCC	*1012WCA*
DQE(0)	*0.778*	*0.753*
	1012WGC	*1210SGA*
DQE(0)	*0.437*	*0.470*

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 subjects,1012WCC and 1012WGC, have been evaluated and compared to 1012WCA and 1210SGA, respectively, 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 1012WCC/1012WGC and the 1012WCA/1210SGA, the images obtained with the 1012WCC/1012WGC were superior to the same view obtained from a similar patient with the 1012WCA/1210SGA, respectively. In general, both the spatial and soft tissue contrast resolution are superior using the 1012WCC/1012WGC. 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 claims the substantial equivalency between the subject devices and their predicate device 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

For 1012WCC vs 1012WCA

Added function		Risk factor	Discussion
1	Cassette size	-. Essential performance (Image size)	Implemented the cassette size to change total pixel matrix (pixels): 2304x1792, total pixel area: 292.6x227.6, and effective pixel matrix (pixels): 264x1752. The image quality was tested through SSXI Nonclinical/ Clinical test and to be equivalent compared to the predicate device. The revised RM table (Att3-1) include the following risk: for 1012WCC – Operational hazard (Incorrect image data) Highlighted in yellow (HI-601-1-4.3)

For 1012WGC vs 1012SGA

Added function		Risk factor	Discussion
1	Cassette size	-. Essential performance (Image size)	Implemented the cassette size to change total pixel matrix (pixels): 2304x1792, total pixel area: 292.6x227.6, and effective pixel matrix (pixels): 264x1752. The image quality was tested through SSXI Nonclinical/ Clinical test and to be equivalent compared to the predicate device. The revised RM table (Att3-1) include the following risk: for 1012WGC – Operational hazard (Incorrect image data) Highlighted in yellow (HI-601-1-4.3)
2	Wireless	-. Battery	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. 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.
		-. Wireless signal	Att 3-3. 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

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 Rayence Co., Ltd. concludes that 1012WCC and 1012WGC are substantially equivalent in comparison with 1012WCA, the predicate device as described herein.