Rayence Co., Ltd.
℅ Mr. Dave Kim
President
Mtech Group
7707 Fannin St., Ste 200, V111
HOUSTON TX 77054

July 23, 2020

Re: K201796
Trade/Device Name: 1717SCV, 1717SGV
Regulation Number: 21 CFR 892.1680
Regulation Name: Stationary x-ray system
Regulatory Class: Class II
Product Code: MQB
Dated: June 19, 2020
Received: June 30, 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K201796

Device Name
1717SCV / 1717SGV

Indications for Use *(Describe)*

1717SCV and 1717SGV X-ray detectors, 127um and 140um, 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.

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.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

1. 510(k) Summary (K201796)

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 24, 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:	1717SCV / 1717SGV
Model Name	: 1717SCV_127µm, 1717SCV_140µm 1717SGV_127µm, 1717SGV_140µm
Common Name	: Digital Flat Panel X-ray Detector
510(k) Number	
Regulation Number	: 21 CFR 892.1680
Regulation Name	: Stationary X-ray System
Product Code	: MQB
Product Class	: Class 2

Predicate Device #1:

Trade/Device Name	: 1717scc_127um And 1717scc_140um
Common Name	: Digital Flat Panel X-ray Detector
510(k) Number	: K171420
Regulation Number	: 21 CFR 892.1680

Regulation Name	: Stationary X-ray System
Product Code	: MQB
Product Class	: Class 2

Predicate Device #2:

Trade/Device Name	: 1717sgc_127um And 1717sgc_140um
Common Name	: Digital Flat Panel X-ray Detector
510(k) Number	: K171419
Regulation Number	: 21 CFR 892.1680
Regulation Name	: Stationary X-ray System
Product Code	: MQB
Product Class	: Class 2

2. Device Description

1717SCV / 1717SGV 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.

1717SCV and 1717SGV have the same Hardware, Software and components.

The type of scintillator layer are different: Cesium Iodide for 1717SCV and Gadolinium Oxsulfide for 1717SGV. Scintillator is a phosphor that produces scintillations.

The subject detectors are not wireless, but they are connected to a viewing station by ethernet connection. Also, the subject detectors have an Automatic Exposure Control (AEC) feature.

The RAW files can be further processed as DICOM compatible image files by separate console SW (K190866 / Xmaruview V1 (Xmaru Chiroview, Xmaru Podview)/ Rayence Co.,Ltd.) for a radiographic diagnosis and analysis.

The software used with the subject detectors is the same as the software XmaruView V1 used with the predicate K190866.

3. Indication for use

1717SCV and 1717SGV X-ray detectors, 127um and 140um, 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

1717SCV / 1717SGV digital X-ray detector is a modification of 1717SCC (K171420) and 1717SGC (K171419). 1717SCV / 1717SGV was developed for the purpose of retrofitting the stationary X-ray system with a film detector.

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:

1717SCV / 1717SGV detector described in this 510(k) has the same indications for use and similar technical characteristics as its predicate device, 1717SCC (K171420) and 1717SGC (K171419).

5.1 Comparison table

Characteristic	**Proposed** **Rayence Co.,Ltd.** 1717SCV / 1717SGV		**Predicate** **Rayence Co.,Ltd.** 1717SCC and 1717SGC		
Feature					
510(k) number	-		K171420	K171419	
Intended Use	1717SCC and 1717SGC X-ray detectors, 127um and 140um, 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.		1717SCC and 1717SGC X-ray detectors, 127um and 140um, 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.		Same
Detector Type	Amorphous Silicon, TFT		Amorphous Silicon, TFT		Same
Scintillator	1717SCV	CsI:Tl	1717SCC	CsI:Tl	Same
	1717SGV	Gd_2O_2S:Tb	1717SGC	Gd_2O_2S:Tb	
Imaging Area	17 x 17 inches		17 x 17 inches		Same
Pixel matrix	127 : 3328 X 3328 140 : 3072 X 3072		127 : 3328 X 3328 140 : 3072 X 3072		Same
Pixel pitch	127 μm, 140 μm		127 μm, 140 μm		Same
Resolution	127 type: 3.93 lp/mm 140 type: 3.57 lp/mm		127 type: 3.93 lp/mm 140 type: 3.57 lp/mm		Same
A/D conversion	14 / 16 bit		14 bit for 127 μm / 16 bit for 140 μm		Same
MTF (3 lp/mm)	1717SCV	127 type: 0.200 140 type: 0.111	1717SCC	127 type: 0.176 140 type: 0.106	Similar
	1717SGV	127 type: 0.120 140 type: 0.103	1717SGC	127 type: 0.119 140 type: 0.100	
DQE (0.1 lp/mm)	1717SCV	127 type: 0.675 140 type: 0.682	1717SCC	127 type: 0.644 140 type: 0.685	Similar
	1717SGV	127 type: 0.405 140 type: 0.414	1717SGC	127 type: 0.401 140 type: 0.383	
Preview time	≤2		≤2		Same

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	Same
Dimensions	460 x 460 x 15.6 mm	460 x 460 x 15.5 mm	Similar
Weight	4.0 kg	4.0 kg	Same
Application	General Radiology system or Portable system Available with upright stand, table, universal stand.	General Radiology system or Portable system Available with upright stand, table, universal stand.	Same
Power			
Name	RP005A	RS1717	Diffe-rent
Feature			
Type	POE	Power supply	
Rating	Input ; 100-240 V a.c., 50/60 Hz, 1.2 A Output ; 54 V d.c., 0.75 A	Input: AC 100-240V, 50/60Hz 1.0 - 0.5A Output : 24V, 1.60A	
Connection with detector	With LAN cable	With Link cable	

5.2 Scintillator layer

1717SCV and 1717SGV have the same Hardware, Software and components.

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

	Proposed	**Predicate**
CsI (Cesium Iodide)	1717SCV	1717SCC
Gd_2O_2S:Tb (Gadolinium Oxysulfide)	1717SGV	1717SGC

5.3 Recommended 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
			@80 kVp- 630
PXR-321B	Poskom Co.,Ltd.	kVp	125/150
		mA	500

6. Summary of Performance Testing

1717SCV and 1717SGV digital flat panel X-ray detectors in comparison with 1717SCC and 1717SGC have the same indications for use, the same imaging area (17 x 17), based on the same scintillator material (CsI:Tl for SCV and SCC, Gd2O2S:Tb for SGV and SGC), same resolution performance. The pixel matrix for each pixel pitch size (127 um and 140 um) for both the subject devices and the predicate devices are identical. The recommended generator specifications for both the subject device and the predicate device remains the same.

The non-clinical test report for each subject device was prepared and submitted to FDA separately 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 1717SCV and 1717SGV by using the identical test equipment and same analysis method described by IEC 62220-1.

The MTF and DQE represent the ability to visualize object details of a certain size and contrast. 1717SCV and 1717SGV have similar MTF and DQE performance in comparison with 1717 SCC and 1717SGC, respectively, at all spatial frequencies.

The power adapter for 1717SCV and 1717SGV has been updated to RP005A from RS1717.
The electrical safety test data demonstrates that the new power adapter is safe and effective.

7. Summary for any testing in the submission:

- 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 efficiencyDetectors 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”

8. Conclusions:

Based on the non-clinical consideration for both devices, Rayence, the sponsor, claims the substantial equivalency between the subject devices and their predicate devices in terms of diagnostic image quality without new concern for safety and effectiveness.