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

March 27, 2015

Re: K150150
Trade/Device Name: 1717SGN / 1717SCN Digital Flat Panel X-ray Detector
Regulation Number: 21 CFR 892.1680
Regulation Name: Stationary x-ray system
Regulatory Class: II
Product Code: MQB
Dated: January 20, 2015
Received: January 23, 2015

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 A Ochs

Robert Ochs, Ph.D.
Acting 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)*
K150150

Device Name
1717SGN / 1717SCN Digital Flat Panel X-ray Detector

Indications for Use *(Describe)*
1717SGN and 1717SCN Digital Flat Panel X-Ray Detector are indicated for digital imaging solution designed for general radiographic system for human anatomy. They are 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: March 19, 2015

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

Predicate Device :

Manufacturer	: Samsung Mobile Display Co., Ltd.
Device	: LLX240AB01 & LTX240AA01-A
510(k) Number	: K102587 & K090742
Decision Date	: DEC 1, 2010 & SEP 18, 2009

2. Device Description

1717SGN and 1717SCN digital solid state X-ray detectors are based on flat-panel technology. Both radiographic image detector and processing units consist of a scintillator coupled to an a-Si TFTsensor. A digital flat panel X-ray detector 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.

3. Indication for use

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.

4. Summary of Design Control Risk management

1717SGN and 1717SCN digital X-ray detectors are the modification version of LLX240AB01(K102587) and LTX240AA01-A(K090742), respectively.

1717SGN and 1717SCN are slightly smaller in dimensions and substantially lighter in weight than LLX240AB01(K102587) and LTX240AA01-A(K090742).

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:

1717SGN and 1717SCN detector described in this 510(k) have the same indications for use and similar technical characteristics as each predicate device, LLX240AB01(K102587) and LTX240AA01-A(K090742) flat panel detector, manufacturerd by Samsung Mobile Display Co., Ltd.

5.1 Scintillator layer

1717SGN and 1717SCN detector have same Hardware, Software and components except the type of the scintillator layer.

(**scintillator : a phosphor that produces scintillations*)

Scintillator Layer Type	Proposed	Predicate
Gd_2O_2S:Tb (Gadolinium Oxysulfide)	1717SGN	LLX240AB01
CsI (Cesium Iodide)	1717SCN	LTX240AA01-A

5.2 Dimensions and Weight

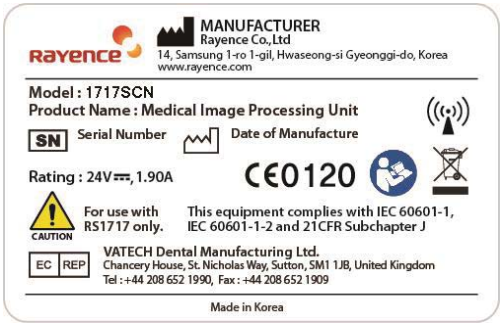
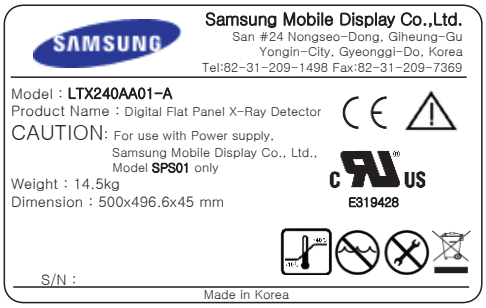
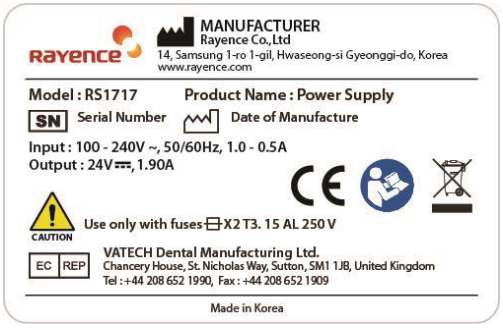
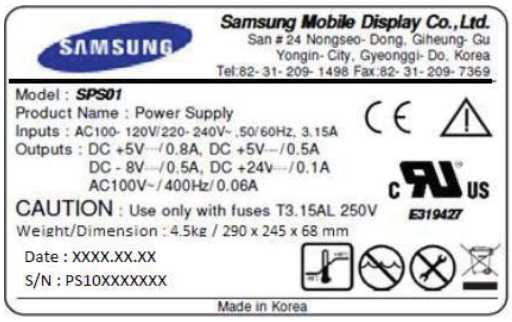
		Proposed 1717SGN 1717SCN	Predicate LLX240AB01 LTX240AA01-A
Detector	Model name	1717SGN	LLX240AB01
	W x L x H	460 X 460 X 15.5	500 x 496.6 x 45mm
	Weight	4 kg	14.5kg
Power supply	Model name	RS1717	SPS01
	W x L x H	188 X 92 X 41.5	290 x 245 x 68 mm
	Weight	0.5 kg	4 kg

5.3 Power Requirements (Power supply)

		Proposed 1717SGN 1717SCN	Predicate LLX240AB01 LTX240AA01-A
Power supply	Model name	RS1717	SPS01
	W x L x H	AC 100 - 240 V~, 50/60Hz	AC100-120 / 220-240 V~, 50/60Hz

5.4 Proposed Labeling

	Proposed 1717SGN 1717SCN	Predicate LLX240AB01 LTX240AA01-A

Detector		
		
Power supply		

5.5 Comparison table

Characteristic	Proposed 1717SGN 1717SCN	Predicate LLX240AB01 LTX240AA01-A

510(k) number	-		LLX240AB01	K102587
			LTX240AA01-A	K090742
Intended Use	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.		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.	
Manufacturer	Rayence Co., Ltd.		Samsung Mobile Display Co., Ltd.	
Detector Type	Amorphous Silicon, TFT		Amorphous Silicon, TFT	
Scintillator	1717SGN	Gd_2O_2S:Tb	LLX240AB01	Gd_2O_2S:Tb
	1717SCN	CsI:Tl	LTX240AA01-A	CsI:Tl
Imaging Area	17 x 17 inches		17 x 17 inches	
Pixel matrix	3072 x 3072 (9 million)		3072 x 3072 (9 million)	
Pixel pitch	127 μm		143 μm	
Resolution	3.9 lp/mm		3.5 lp/mm	
A/D conversion	14 / 16 bit		14 bit	
Preview time	≤2		5 seconds per Image	
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 × 15.5 mm		500 x 496.6 x 45 mm	
Weight	4 kg		14.5 kg	
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.	

6.System requirements to operate with other radiographic system components

1) Recommended Generator Specification:

Energy range: 40~150kVp

mA range 10~1000mA(depending on the generator power)

[NOTE] 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, please contact your Rayence representative.

2) **S**oftware **D**evelopment **K**it (Library's Software Interface) for third party viewing software

Peripheral hardware: DaVinci detector connected via Ethernet card.

CPU/Motherboard: 1 GHz (or faster) CPU, cache L2≥256KB

RAM: ≥512MB, 2GB recommended

Hard drive: no special requirements

Display: At least 17-inch monitor is required. 21-inch monitor is suggested.

OS: Windows 2K or XP professional

Development environment: MS Visual C++ 6.0 or MS Visual Studio 2005

7. Summary of Performance Testing

1717SGN and 1717SCN Digital Flat Panel X-Ray Detector have the same indications for use, material, form factor, performance, and safety characteristics compared to the predicate devices, LLX240AB01 and LTX240AA01-A, respectively.

The non-clinical test report and clinical consideration report for each subject device were 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 1717SGN and 1717SCN by using the identical test equipment and same analysis method described by IEC 62220-1. The comparative result of the MTF test for 1717SGN and 1717SCN detector with respect to each respective predicate demonstrated that the MTF of the both 1717SGN and 1717SCN performed better compared with the predicate devices. The DQE represents the ability to visualize object details of a certain size and contrast. 1717SGN demonstrated higher DQE performance than LLX240AB01 at all spatial frequencies as well as superior Signal-to Noise Ratio (SNR) transfer from the input to the output of the detector as a function of frequency. 1717SCN has higher DQE performance at high spartial frequencies, especially from 1lp/mm to 3 lp/mm.

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 (1717SGN and 1717SCN) and control group (LLX240AB01 and LTX240AA01-A) 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.

After comparing a broad review of plain radiographic images taken with 1717SGN / 1717SCN and LLX240AB01 / LTX240AA01-A, the images obtained with the 1717SGN / 1717SCN are comparable or superior to the same view obtained from a similar patient with the LLX240AB01 / LTX240AA01-A. In general, both the spatial resolution and soft tissue contrast are superior

using the 1717SGN / 1717SCN digital flat panel detector. 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.

Clinical images were provided; these images were not necessary to establish substantial equivalence based on the modifications to the device but they provide further evidence in addition to the laboratory performance data to show that the subject devices operate as indicated.

Based on the non-clinical bench testing supplemented by the clinical consideration and the outcome of a comparative review by an expert for both devices, the sponsor demonstrated that the subject devices operate as indicated and are substantially equivalent to the predicate devices in terms of safety and effectiveness.

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.

8. 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.

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 1717SGN / 1717SCN are safe and effective and substantially equivalent in comparison with LLX240AB01 / LTX240AA01-A, the predicate devices as described herein.