FEB 21 2014

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: November 5th, 2013

Submitter's Name, address, telephone number, a contact person:

Submitter's Name :	Rayence Co., Ltd.
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Submitter's Telephone:	+82-31-8015-6459
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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:	910SGA
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	: 1210SGA
510(k) Number	: K113630 (Decision Date – DEC. 29. 2011)

Device Description :

910SGA 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 :

910SGA Digital Flat Panel X-Ray Detector is indicated for digital imaging solution designed for human anatomy including head, neck, spinal column, 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 professionals. Not to be used for mammography.

Summary of the technological characteristics of the device compared to the predicate device:

The 910SGA SSX1 detector described in this 510(k) has the same indications for use and similar technical characteristics as its predicate device, 1210SGA flat panel detector, of Rayence Co., Ltd. Table 1 summarizes the technological characteristics of the 910SGA and 1210SGA, the predicate device.

Table 1: Comparison of 910SGA and 1210SGA

Characteristic	Proposed Rayence Co.,Ltd. *910SGA*	Predicate Rayence Co.,Ltd. *1210SGA*
510(k) number	-	K113630
Intended Use	910SGA Digital Flat Panel X-Ray Detector is indicated for digital imaging solution designed for human anatomy including head, neck, spinal column, 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 professionals. Not to be used for mammography.	1210SGA Digital Flat Panel X-Ray Detector is indicated for digital imaging solution designed for human anatomy including head, neck, spinal column, 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 professionals. Not to be used for mammography.
Detector Type	Amorphous Silicon with TFT	Amorphous Silicon with TFT
Scintillator	Gadolinium Oxysulfide	Gadolinium Oxysulfide
Imaging Area	9x 10 inches	11 x 13 inches
Total Pixel Matrix	2048 x 1792 pixels	2560 x 2080 pixels
Pixel pitch	127 μm	127 ㎛
Resolution	3.9 lp/mm	3.9lp/mm
A/D conversion	14 bit	14 bit
Preview Image	≤4 seconds	3~4 seconds
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	314 X 279 X 23.5 mm	402 × 364 × 32 mm

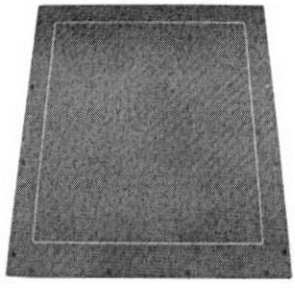
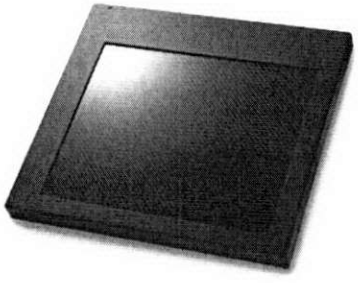
Weight	2.0 kg	3.0 kg
Application	adults and pediatric care	adults and pediatric care
Feature		

Table 2: Size Comparison of 910SGA and 1210SGA

Item	Unit	910SGA	1210SGA
Pixel Pitch	μm	127 x 127	127 x 127
Total Pixel Matrix	pixels	2048 x 1792	2560 x 2080
Total Pixel Area	mm	260.1 x 227.6	264 x325
Effective Pixel Matrix	pixels	2008 x 1752	2520 x 2040
Fill factor	%	61.03	65.14
Weight	Kg	2.0 Kg	3.0 Kg

Summary of Performance Testing:

The 910SGA flat panel detector is a modified version of 1210SGA (K113630), FDA cleared predicate device from Rayence. Indications for use, material, form factor, performance, and safety characteristics between 910SGA and 1210SGA 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 910SGA and 1210SGA by using the identical test equipment and same analysis method described by IEC 62220-1 The comparison of the MTF for 910SGA and 1210SGA detector demonstrated that the MTF of the 910SGA detector performed almost same with 1210SGA. Therefore the overall resolution performance and sharpness of 910SGA is almost same with 1210SGA. The DQE represents the ability to visualize object details of a certain size and contrast. 910GA demonstrated higher DQE performance than 1210GA 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, 910SGA has a DQE

of 46% and that of 1210SGA is 45%. 910SGA also exhibited NPS which has almost same performance with 1210SGA. Therefore, the image quality of 910SGA is found to be substantially equivalent to 1210SGA 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 (910SGA) and control group (1210SGA) 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 910SA and its predicate device, 1210SGA in terms of image quality.

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, Class A.
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.

The manufacturing facility is in conformance with the design control procedure requirements as specified in 21 CFR 802.30 and the records are available for review.

All test results were satisfactory.

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 910SGA is safe and effective and substantially equivalent in comparison with 1210SGA, 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

February 21, 2014

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

Re: K133409
Trade/Device Name: Digital Flat Panel X-ray Detector/ 910sga
Regulation Number: 21 CFR 892.1680
Regulation Name: Stationary x-ray system
Regulatory Class: II
Product Code: MQB
Dated: January 17, 2014
Received: January 23, 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.

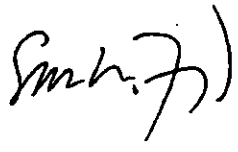
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further 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)*
K133409

Device Name
910SGA Digital Flat Panel X-Ray Detector

Indications for Use *(Describe)*

910SGA Digital Flat Panel X-Ray Detector is indicated for digital imaging solution designed for human anatomy including head, neck, spinal column, 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 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 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)*

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