K122928

510(k) Summary

JAN 3 0 2013

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: September 21, 2012

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

Submitter's Name :	Rayence Co., Ltd.
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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:	1417PGA
Common Name:	Digital Flat Panel X-ray Detector
Classification Name :	Solid State X-ray Imaging Device, Class2
Regulation Number / Name:	21CFR 892.1680 / Stationary X-ray system

Product Code: MQB

Predicate Device :

Manufacturer	: Samsung Mobile Display Co., Ltd.
Device	: SDX-4336CP
510(k) Number	: K102321 (Decision Date - Feb. 11. 2011)

Device Description :

The 1417PGA is a portable digital X-ray flat panel detector that can generate images of any part of the body. This X-ray imaging system consists of a scintillator directly coupled to an a-Si TFT sensor. It makes high-resolution, high-sensitive digital images. 1417PGA is designed specifically to be integrated with an operating PC and a X-ray generator to digitalize X-ray images into RAW files. The RAW files can be made to DICOM compatible image files for a radiographic diagnosis and analysis by console SW.

Indication for use :

1417PGA 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.

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

1417PGA SSXI detector described in this 510(k) has the same indications for use and similar technical characteristics as its predicate device, SDX-4336CP, of Samsung Mobile Display Co., Ltd. Table 1 summarizes the technological characteristics of the 1417PGA and SDX-4336CP the predicate device.

Table 1: Comparison of 1417PGA and SDX-4336CP

Characteristic	**Proposed** **Rayence Co.,Ltd.** ***1417PGA***	**Proposed** **Samsung Mobile Display Co., Ltd.** ***SDX-4336CP***
510(k) number	-	K102321
Intended Use	1417PGA 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.	SDX-4336CP Digital Flat Panel X-Ray Detector is indicated for digital imaging solution designed for providing general radiographic diagnosis of human anatomy targeting both adult and children. It is intended to be used by physicians and radiologists and not to be used for mammography.
Detector Type	Amorphous Silicon, TFT	Amorphous Silicon, TFT
Scintillator	Gadolinium Oxysulfide	Cesium Iodide
Imaging Area	14 x 17 inches	14 x 17 inches
Pixel matrix	3328 x 2816 (9.4 million)	2880 x 2400 (6.9 million)
Pixel pitch	127 ㎛	150 ㎛
Resolution	3.9lp/mm	3.3lp/mm

A/D conversion	14 bit	14 bit
Grayscale	16384 (14bit)	16384 (14bit)
Preview Image	2~3 seconds	2~3 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	460 x 417 x 15.9 mm	491 × 480 × 15 mm
Weight	3.6 kg	3.8 kg
Application	Portable system Available with upright stand, table, universal stand	Portable system Available with upright stand, table, universal stand
Feature		

Table 2: Comparison of 1417PGA and SDX-4336CP

Item	Unit	1417PGA	SDX-4336CP
Pixel size	μm	127 x 127	150 x 150
Total horizontal and vertical size	mm	422.7 x 357.6	432 x 360
Total horizontal and vertical element count	pixels	3328 x 2816	2880 x 2400
Active area horizontal and vertical size	mm	416.6 x 351.8	423 x 351
Active area horizontal and vertical element count	pixels	3280 x 2770	2820 x 2340
Pixel spacing	um	127	150
Fill factor	%	65.14	68.5
Weight	Kg	3.6 Kg	3.8 Kg

Summary of Performance Testing:

Indications for use, material, form factor, performance, and safety characteristics between 1417PGA and the predicate device are very similar. The primary difference is Pixel size, Pixel matrix, Pixel pitch, Resolution and Scintillator materials; GdOS(Gd2O2S:Tb) for 1417PGA and Cesium iodide(CsI) for SDX-4336CP, respectively. The non-clinical test report and clinical consideration report were prepared and submitted to FDA separately to demonstrate the substantial equivalency between two different detectors. The non-clinical test report contains the MTF, DQE and NPS test results of 1417PGA and SDX-4336CP by using the identical test equipment and same analysis method described by IEC 62220-1. The comparisoin of the MTF for 1417PGA and SDX-4336CP detector demonstated that the MTF of the 1417PGA detector performed better than SDX-4336CP at 0~2.2 lp/mm. Also, the new detector 1417PGA utilizes a new bonding mechanism to narrow the gap between the panel and scintillator. Moreover, the pixel size of the new detector 1417PGA is 127 μm which is smaller than 143 μm of SDX-4336CP. Thereofre, the overall resolution performance and sharpness of 1417PGA is better than SDX-4336CP which results improvement of the ability of the new detector to represent distinct anatomic features whitin the imaged object. The DQE represents the ability to visualize object details of a certain size and contrast. 1417PGA demonstrated better DQE performance than SDX-4336CP at various spatial frequencies and provides a higher Signal-toNoise Ratio (SNR) transfer from the input to the output of a detector as a function of frequency. At the zero-frequency DQE values for 1417PGA is higher than SDX-4336CP; 0.761 and 0.740 respectively. The reduced noise has imporved the accuracy of image and reduced the degree of artifacts for the new detector. 1417PGA exhibited NPS which has lower performance than SDX-4336CP. Therefore, the image quality of 1417PGA is greater than SDX-4336CP at the same patient exposure.

To further demonstrate the substantial equivalency of two devices, clinical images are taken from both devcies and reviewd by a licensed US radiologist to render an expert opinion. Both test (1417PGA) and control group (SDX-4336CP) are evaluated according to age group and anatomical structures were compared in accordance with the test protocol of diagnostic radiography evaluation procedure.

Based on the non-clinical and clinical consideration and the outcome of an expert review of image comparisions for both devices, we can claim equivalent or better diagnostic image quality for1417PGA compared to the predicate device, SDX-4336CP.

Safety, EMC and Performance Data :

Electrical, mechanical, environmental safety and performance testing according to standard IEC 60601-1:1998+A1:1999+A2:1995(Medical electrical equipment Part 1: General Requirements for Safety) was performed, and EMC testing were conducted in accordance with standard (Medical electrical equipment – Part 1-2: General Requirements for safety – Collateral Standard : Electromagnetic Compatibility Requirements and tests).

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.

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 1417PGA is safe and effective and substantially equivalent in comparison with 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

January 30, 2013

Rayence Co., LTD.
C/O Dave Kim
Mtech Group
12946 Kimberley Lane
HOUSTON TX 77079

Re: K122928
Trade/Device Name: Digital Flat Panel X-ray Detector 1417PGA
Regulation Number: 21 CFR 892.1680
Regulation Name: Stationary x-ray system
Regulatory Class: II
Product Code: MQB
Dated: January 16, 2013
Received: January 26, 2013

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 go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. 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,

Sean M. Boyd -S for

Janine M. Morris
Director, Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K122928

Device Name: Digital Flat Panel X-Ray Detector /1417PGA

Indications for Use:

1417PGA 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.

Prescription Use ___X____ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of *In Vitro* Diagnostics and Radiological Health (OIR)

Sean M. Boyd -S

(Division Sign Off)
Division of Radiological Health
Office of *In Vitro* Diagnostic and Radiological Health

510(k)___122928_____