K122173

Special 510(k) Summary

OCT 19 2012

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: August 31st, 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:	1717SCC
Common Name:	Digital Flat Panel X-ray Detector
Classification Name :	21CFR 892.1650, Solid State X-ray Imaging Device, Class2
Product Code:	MQB

Predicate Device :

Manufacturer	: Rayence Co.,Ltd.
Device	: Xmaru1717
510(k) Number	: K091090 (Decision Date - SEP 9. 2010)

Device Description :

1717SCC 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 :

1717SCC 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:

The 1717SCC SSXI detector described in this 510(k) has the same indications for use and similar technical characteristics as its predicate device, Xmaru1717, of Rayence Co., Ltd. Table 1 summarizes the technological characteristics of the 1717SCC and Xmaru1717 the predicate device.

Table 1: Comparison of 1717SCC and Xmaru1717

Characteristic	**Proposed** **Rayence Co.,Ltd.** ***1717SCC***	**Predicate** **Rayence Co.,Ltd.** ***Xmaru1717***
510(k) number	-	K091090

Intended Use	1717SCC 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.	Xmaru1717 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.
Detector Type	Amorphous Silicon, TFT	Amorphous Silicon, TFT
Scintillator	Cesium Iodide	Gadolinium Oxysulfide
Imaging Area	17 x 17 inches	17 x 17 inches
Pixel matrix	3328 x 3328 (10 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 bit	14 bit
Grayscale	16384 (14bit)	16384 (14bit)
Preview Image	3~4 seconds	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 × 15.9 mm	500 x 497 x 45 mm
Weight	5.3 kg	13.4 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.

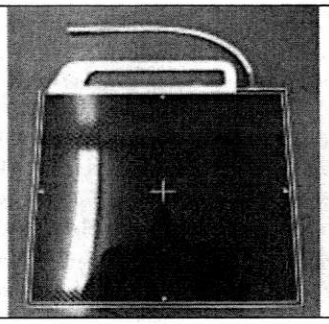
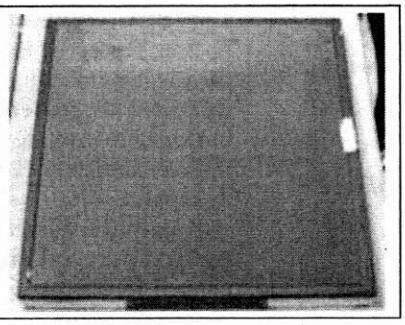
Feature		

Table 2: Comparison of 1717SCC and Xmaru1717

Item	Unit	1717SCC	Xmaru1717
Pixel size	μm	127 x 127	143 x 143
Total horizontal and vertical size	mm	426 x 426	439 x 439
Total horizontal and vertical element count	pixels	3328 x 3328	3072 x 3072
Active area horizontal and vertical size	mm	426 x 426	429 x 429
Active area horizontal and vertical element count	pixels	3250 x 3250	3000 x 3000
Pixel spacing	um	127	143
Fill factor	%	63	68.30
Weight	Kg	5.3 Kg	13.4 Kg

Note: The weight of new sensor differs from the predicate sensor (Xmaru1717).

1. Change of the case material : The new sensor casing is done with stainless steel (lighter) instead of Aluminum (heavier). The result is approximately 5kg less weight for 1717 SCC detector compared with the Xmaru1717 detector, predicate device.

2. Panel : Unlike the new detector, the previous detector is bonded with the sub-glass panel, (the thickness of 2.9mm). The result is approximately 1.5kg less weight for 1717SCC.

3. Lighter Main BD Block(Structure between the Panel and Main BD) : Approximately 1kg less weight

4. Lighter Main BD : Approximately 0.7kg less weight

Summary of Performance Testing:

Indications for use, material, form factor, performance, and safety characteristics between 1717SCC and the predicate device are very similar. The primary difference is Pixel size, Pixel matrix, Pixel pitch, Resolution and Scintillator materials; Cesium iodide(CsI) for 1717SCC and GOS(Gd2O2S:Tb) for Xmaru1717, 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 1717SCC and Xmaru1717 by using the identical test equipment and same analysis method described by IEC 62220-1 The comparisoin of the MTF for 1717SCC and Xmaru1717 detector demonstated that the MTF of the Xmaru1717 detector performed better than 1717SCC. Nevertheless, the new detector 1717SCC utilizes a new bonding mechanism to narrow the gap between the panel and scintillator. Moreover, the pixel size of the new detector 1717SCC is 127 μm smaller than 143 μm of Xmaru1717. Thereofre, the overall resolution performance and shapness of 1717SCC is better than Xmaru1717 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. 1717SCC demonstrated better DQE performance than Xmaru1717 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 1717SCC is much lower than Xmaru1717; 0.223 and 0.38 respectively. The reduced noise has imporved the accuracy of image and reduced the degree of artifacts for the new detector. 1717SCC exhibited NPS which has lower performance than Xmaru1717. Therefore, the image quality of 1717SCC is greater than Xmaru1717 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 (1717SCC) and control group (Xmaru1717) 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 for1717SCC compared to the predicate device, Xmaru1717.

Safety, EMC and Performance Data :

Electrical, mechanical, environmental safety and performance testing according to standard IEC 60601-1:2005(Medical electrical equipment – Part 1: General requirements for basic safety and essential performance) + CORR.1(2006) + CORR.2 (2007) / EN 60601-1:2006 was performed, and EMC testing were conducted in accordance with standard IEC 60601-1-2:2007(Medical electrical equipment – Part 1-2: General Requirements for safety – Collateral Standard :

Electromagnetic Compatibility Requirements and tests) / EN 60601-1-2:2007. 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 1717SCC 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
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Document Control Room – WO66-G609
Silver Spring, MD 20993-0002

OCT 19 2012

Rayence Co., Ltd.
% Mr. Dave Kim
Medical Device Regulatory Affairs
Mtech Group
12946 Kimberely Lane
HOUSTON TX 77079

Re: K122173
Trade/Device Name: Digital Flat Panel X-Ray Detector/1717SCC
Regulation Number: 21 CFR 892.1650
Regulation Name: Image-intensified fluoroscopic x-ray system
Regulatory Class: II
Product Code: MQB
Dated: July 13, 2012
Received: August 20, 2012

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.

If your device is classified (see above) into class II (Special Controls), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. 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 Parts 801 and 809); medical device reporting (reporting of

medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Parts 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. 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 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/cdrh/industry/support/index.html.

Sincerely Yours,

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): K122173

Device Name: Digital Flat Panel X-Ray Detector /1717SCC

Indications for Use:

1717SCC 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 ✔ AND/OR Over-The-Counter Use_____

(Part 21 CFR 801 Subpart D) (Part 21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation(ODE)

(Division Sign Off)

Division of Radiological Health

Office of In Vitro Diagnostics and Radiological Health

510(k) K122173