510(k) Summary

JUL 0 2 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: March 26, 2013

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

Submitter's Name :	Rayence Co., Ltd.
Submitter's Address:	1F, 2F, 3F, #402, 14, Samsung 1-ro 1-gil, Hwaseong-si, Gyeonggi-do, Korea
Submitter's Telephone:	+82-31-8015-6459
Contact person:	Mr. Kee Dock Kim / Manager
Official Correspondent: (U.S. Designated agent)	Dave Kim (davekim@mtech-inc.net)
Address:	12946 Kimberley Ln, Houston, TX 77079
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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:	1417WCA
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	: 1417PCA
510(k) Number	: K122919 (Decision Date – JAN. 31. 2013)

Device Description :

1417WCA is a wired/wireless digital X-ray flat panel detector that can acquire radiographic images of human anatomy when used with existing radiographic x-ray systems. The wireless LAN((IEEE 802.11a/g/n) communication signals images captured to the system and improves the user operability through high-speed processing. This X-ray imaging detector consists of a scintillator directly coupled to an a-Si TFT sensor. 1417WCA is designed specifically to be integrated with a console PC system and X-Ray generator to digitalize x-ray images into RAW files. The RAW files can be made to DICOM compatible image files which can be viewed by console SW for a radiographic image diagnosis and analysis.

Indication for use :

1417WCA 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 1417WCA SSXI detector described in this 510(k) has the same indications for use and similar technical characteristics as its predicate device, 1417PCA flat panel detector, of Rayence Co., Ltd. Table 1 summarizes the technological characteristics of the 1417WCA and 1417PCA, the predicate device.

Table 1: Comparison of 1417WCA and 1417PCA

Characteristic	Proposed Rayence Co.,Ltd. *1417WCA*	Predicate Rayence Co.,Ltd. *1417PCA*
510(k) number	-	-K122919
Intended Use	1417WCA 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.	1417PCA 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	Cesium Iodide
Imaging Area	14 x 17 inches	14 x 17 inches
Total Pixel Number	3328 x 2816 pixels	3328 x 2816 pixels
Pixel pitch	127 μm	127 μm
Resolution	3.9 lp/mm	3.9lp/mm
A/D conversion	14 bit	14 bit
Preview Image	2~3 seconds (wired) / 3~5 seconds (wireless)	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	460 x 417 x 15.9 mm

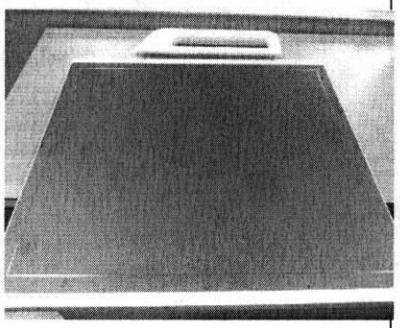
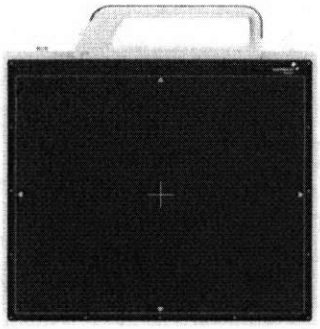
Weight	3.9 kg (incl. battery pack)	3.6 kg
Application	Wireless portable system Available with upright stand, table, universal stand	Portable system Available with upright stand, table, universal stand
Feature		

Table 2: Size Comparison of 1417WCA and 1417PCA

Item	Unit	1417WCA	1417PCA
Pixel Pitch	μm	127 x 127	127 x 127
Total Pixel Number	pixels	3328 x 2816	3328 x 2816
Effective Pixel Area	mm	415 x 350	415 x 350
Effective Pixel Number(light sensitive)	pixels	3268x 2756	3268x 2756
Fill factor	%	61.03	61.03
Weight	Kg	3.9 Kg	3.6 Kg

Summary of Performance Testing:

The wireless/wired 1417WCA flat panel detector is a modified version of 1417PCA (K122919), FDA cleared predicate device from Rayence. Indications for use, material, form factor, performance, and safety characteristics between 1417WCA and 1417PCA are the same. 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 1417WCA and 1417PCA by using the identical test equipment and same analysis method described by IEC 62220-1 The comparisoin of the MTF for 1417WCA and 1417PCA detector demonstated that the MTF of the 1417WCA detector performed almost same with 1417PCA. Therefore the overall resolution performance and shapness of 1417WCA is almost same with 1417PCA. The DQE represents the ability to visualize object details of a certain size and contrast. 1417WCA demonstrated almost same DQE

performance with 1417PCA at various spatial frequencies and provides almost same Signal-toNoise Ratio (SNR) transfer from the input to the output of a detector as a function of frequency. At the lowest spatial frequency, the DQE test for 1417WCA and 1417 PCA resulted 74% and 76%, respectively. The NPS test for 1417WCA and 1417 PCA exhibited almost identical performance between the two devices. Therefore, the image quality of 1417WCA is substantially equivalent to 1417PCA at the same patient exposure setting.

To further demonstrate the substantial equivalency of two devices, clinical images are obtained from both devcies and reviewd by a licensed US radiologist to render an expert opinion. Both the test (1417WCA) and control group (1417PCA) are evaluated according to similar 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 test and the outcome of a comparative review by an expert for both devices, we can claim the substantial equivalency between 1417WCA and its predicate device, 1417PCA in terms of image quality.

Safety, EMC and Performance Data :

Electrical, mechanical, environmental safety and performance testing according to standard IEC 60601-1:1988 + A1:1991 + A2:1995 (Medical electrical equipment Part 1: General Requirements for Safety) was performed, and EMC testing were conducted in accordance with standard IEC60601-1-2:2007 (CISPR 11:2009/A1: 2010), EN60601-1-2:2007 +A1:2010 (Medical electrical equipment – Part 1-2: General Requirements for safety – Collateral Standard : Electromagnetic Compatibility Requirements and tests). The equipment also complies with the standard FCC Rule part(s) 47CFR PART 15.107(B) / 47CFR PART 15.109(G) CLASSB.
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 1417WCA is safe and effective and substantially equivalent in comparison with 1417PCA, 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

July 2, 2013

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

Re: K130935
Trade/Device Name: Digital Flat Panel X-ray Detector / 1417WCA
Regulation Number: 21 CFR 892.1680
Regulation Name: Stationary x-ray system
Regulatory Class: II
Product Code: MQB
Dated: April 04, 2013
Received: April 04, 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.

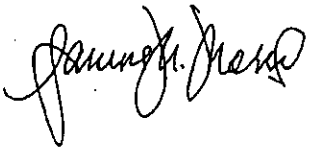
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further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



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): K130935

Device Name: Digital Flat Panel X-ray Detector / 1417 WCA

Indications for Use:

1417WCA 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) (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)

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

510(k) K130935