K123345
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MAR 1 2 2013

Special 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: October 22, 2012

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:	1012WCA
Common Name:	Digital Flat Panel X-ray Detector
Classification Name :	21CFR 892.1680, Stationary X-ray System, Solid State X-ray Imaging Device, Class2
Product Code:	MQB

Predicate Device :

Manufacturer	: Rayence Co., Ltd.
Device	: Xmaru1210P
510(k) Number	: K101590 (Decision Date - NOV 29. 2010)

Device Description :

1012WCA 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. 1012WCA 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 :

1012WCA Digital Flat Panel X-Ray Detector is indicated for digital imaging solution designed for human anatomy including head, neck, cervical spine, 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 care professionals. Not to be used for mammography.

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

The 1012WCA SSXI detector described in this 510(k) has the same indications for use and similar technical characteristics as its predicate device, Xmaru1210P flat panel detector, of Rayence Co., Ltd. Table 1 summarizes the technological characteristics of the 1012WCA and Xmaru1210P, the predicate device.

Table 1: Comparison of 1012WCA and Xmaru1210P

Characteristic	**Proposed** **Rayence Co.,Ltd.** ***1012WCA***	**Predicate** **Rayence Co.,Ltd.** ***Xmaru1210P***
510(k) number	-	K101590
Intended Use	1012WCA Digital Flat Panel X-Ray Detector is indicated for digital imaging solution designed for human anatomy including head, neck, cervical spine, 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 care professionals. Not to be used for mammography.	Xmaru1210P 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 care professionals. Not to be used for mammography.
Detector Type	Amorphous Silicon, TFT	Amorphous Silicon, TFT
Scintillator	Cesium Iodide	Cesium Iodide
Imaging Area	11 x 13 inches	11 x 13 inches
Pixel matrix	2080 x 2560 (5.3 million)	2080 x 2560 (5.3 million)
Pixel pitch	127 μm	127 μm
Resolution	3.9 lp/mm	3.9 lp/mm
A/D conversion	16 bit	14 bit
Grayscale	65536(16bit)	16384 (14bit)

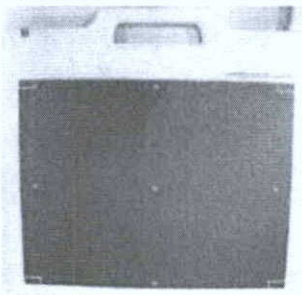
Preview Image	3 seconds	6.5 seconds
Data output	DICOM 3.0 compatible Print Management Service Class(SCU), Storage Service Class(SCU), and others DICOM Patient CD DICOM Basic Print	DICOM 3.0 compatible Print Management Service Class(SCU), Storage Service Class(SCU), and others DICOM Patient CD DICOM Basic Print
Dimensions	395 x 337 x 18 mm	422 x 403 x 22 mm
Weight	3.15 kg (incl. battery pack)	3.4 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 1012WCA and Xmaru1210P

Item	Unit	1012WCA	Xmaru1210P
Pixel size	μm	127 x 127	127 x 127
Total horizontal and vertical size	mm	264 x 325	264 x 325
Total horizontal and vertical element count	pixels	2080 x 2560	2080 x 2560
Active area horizontal and vertical size	mm	259 x 320	259 x 320
Active area horizontal and vertical element count	pixels	2040 x 2520	2040 x 2520
Pixel spacing	um	127	127
Fill factor	%	65.14	65.14
Weight	Kg	3.15 Kg	3.4 Kg

Summary of Performance Testing:

The wireless/wired 1012WCA flat panel detector is a modified version of Xmaru1210P, FDA cleared under the document number K101590. Indications for use, material, form factor, performance, and safety characteristics between 1012WCA and Xmaru1210P, the predicate device 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 1012WCA and Xmaru1210P by using the identical test equipment and same analysis method described by IEC 62220-1 The comparison of the MTF for 1012WCA and Xmaru1210P detector demonstrated that the MTF of the Xmaru1210P detector performed better than 1012WCA. Nevertheless the overall resolution performance and sharpness of 1012WCA is better than Xmaru1210P which results improvement of the ability of the new detector to represent distinct anatomic features within the imaged object. The DQE represents the ability to visualize object details of a certain size and contrast. 1012WCA demonstrated better DQE performance than Xmaru1210P at various spatial frequencies and provides a higher Signal-to-Noise Ratio (SNR) transfer from the input to the output of a detector as a function of frequency. The reduced noise has improved the accuracy of image and reduced the degree of artifacts for the new detector. Also, the image quality of 1012WCA is greater than Xmaru1210P 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 test (1012WCA) and control group (Xmaru1210P) 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 comparisons for both devices, we can claim equivalent or better diagnostic image quality of the 1012WCA flat panel detector compared to the predicate device, Xmaru1210P.

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 IEC 60601-2 (Medical electrical equipment Part 2: General Requirements for safety – Collateral Standard : Electromagnetic Compatibility Requirements and tests). FCC part 15 subpart B and C, Class A.

All test results were satisfactory.

Conclusions :

The performance data demonstrates that the 1012WCA SSXI detector is as safe and effective as its predicate device, Xmaru1210P. Based on the information in this submission, similarity to the predicate device, and the results of our design control activities, it is our opinion that the 1012WCA flat panel detector is substantially equivalent to the predicate device, Xmaru1210P.

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

March 12, 2013

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

Re: K123345
Trade/Device Name: Digital Flat Panel X-Ray Detector/1012WCA
Regulation Number: 21 CFR 892.1680
Regulation Name: Stationary x-ray system
Regulatory Class: II
Product Code: MQB
Dated: February 8, 2013
Received: February 11, 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,

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): K123345

Device Name: Digital Flat Panel X-ray Detector/1012WCA

Indications for Use:

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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)

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

510(k) K123345