



Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

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

April 8, 2016

Re: K160579

Trade/Device Name: Xmaru View V1(Xmaru Chiroview or Xmaru Podview) and Xmaru
PACS, Medical Image Processing Software

Regulation Number: 21 CFR 892.2050

Regulation Name: Picture archiving and communications system

Regulatory Class: II

Product Code: LLZ

Dated: February 26, 2016

Received: March 1, 2016

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 Industry and Consumer Education 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” (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 Industry and Consumer Education 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,

A handwritten signature in blue ink that reads "Michael D. O'Hara". The signature is written in a cursive style and is positioned above the typed name and title.

FOR

Robert Ochs, Ph.D.
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)
K160579

Device Name
XmaruView V1(Xmaru Chiroview or Xmaru Podview) and Xmaru PACS
Medical Image Processing Software

Indications for Use (Describe)

XmaruView V1(Xmaru Chiroview or Xmaru Podview) software carries out the image processing and administration of medical X-ray data which includes adjustment of window leveling, rotation, zoom, and measurements. XmaruView V1(Xmaru Chiroview or Xmaru Podview) is not approved for mammography and is meant to be used by qualified medical personnel only. XmaruView V1(Xmaru Chiroview or Xmaru Podview) is complying with DICOM standards to assure optimum communications between network systems.

Xmaru PACS receives, stores, searches and views the diagnostic image data from imaging modalities in DICOM compliant. Xmaru PACS is capable of communicating with electronic medical records systems, hospital information systems, and radiology information system via DICOM standard.

XmaruView V1(Xmaru Chiroview or Xmaru Podview) and Xmaru PACS can be packaged together or offered as a stand-alone imaging solution to be installed in a PC for trained medical professionals.

Type of Use (Select one or both, as applicable)

Prescription Use (Part 21 CFR 801 Subpart D)

Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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1. 510(k) Summary

This summary of 510(k) information is being submitted in accordance with requirements of 21 CFR Part 807.92.

Date 510K summary prepared: FEB. 26, 2016

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

Submitter's Name : Rayence Co., Ltd.
Submitter's Address: 14, Samsung 1-ro 1-gil, Hwaseong-si, Gyeonggi-do, Korea
Submitter's Telephone: +82-31-8015-6459
Contact person: Mr. Kee Dock Kim / RA Team Manager / +82-31-8015-6459
Official Correspondent: Dave Kim (davekim@mtech-inc.net)
Address: 8310 Buffalo Speedway, Houston, TX 77025
Telephone: +713-467-2607
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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:

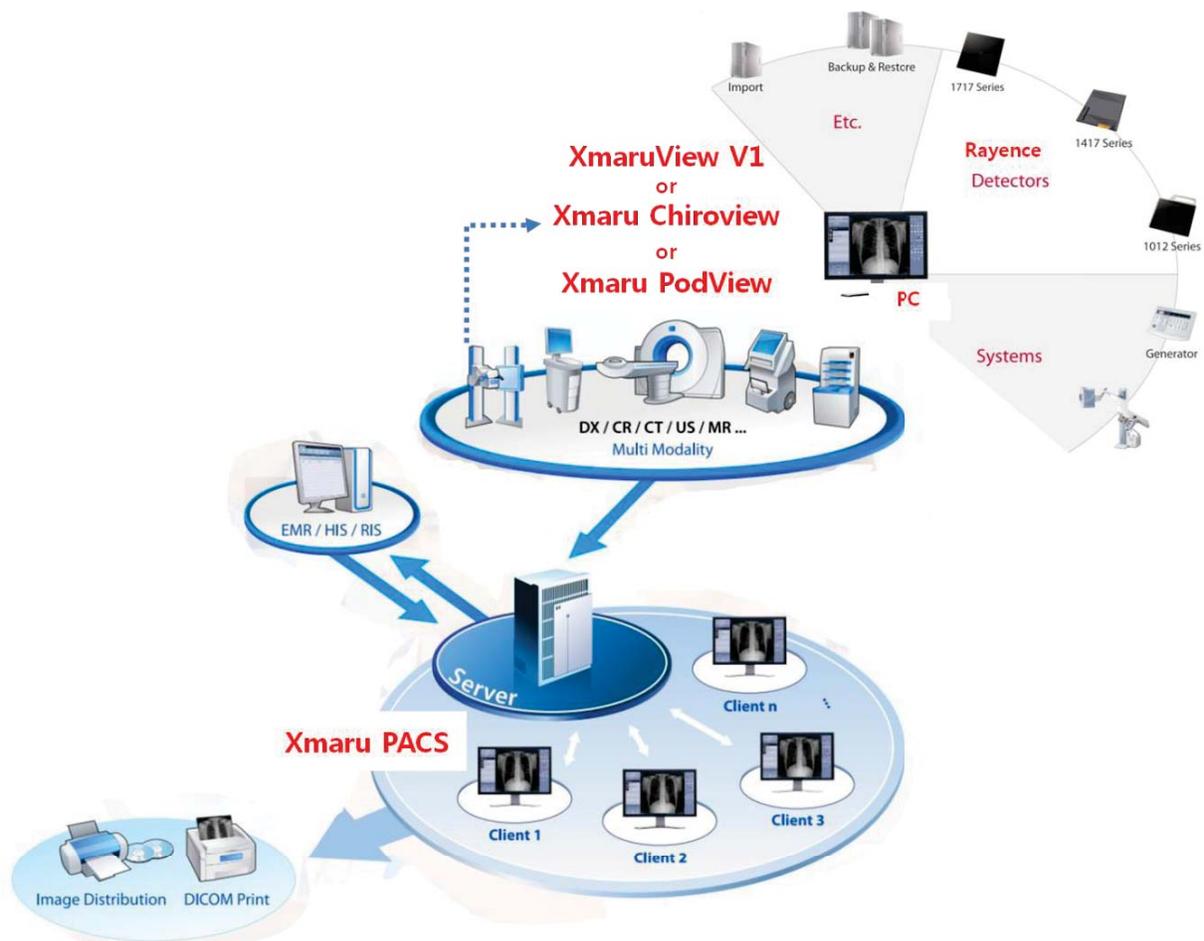
Trade/proprietary name: XmaruView V1, Xmaru Chiroview, Xmaru Podview and Xmaru PACS
Common Name: Medical Image Processing Software
Regulatoin number: 21 CFR 892.2050
Classification Name : System, Image Processing, Radiological
Product Code: LLZ

2. Device Description

XmaruView V1(Xmaru Chiroview or Xmaru Podview) is a software program designed to provide image acquisition, processing and operational management functions for digital radiography.

XmaruView V1(Xmaru Chiroview or Xmaru Podview) controls a flat-panel detector and a X-ray generator to acquire digital images. The software also manages patient information, capture and store diagnostic images in an internal database. It also supports DICOM which allows compatibility with other radiography equipment and network programs. XmaruView V1(Xmaru Chiroview or Xmaru Podview) provides a streamlined and optimized process of multiple workflows in any hospital environment for digital radiography.

Xmaru PACS is in charge of receiving the images from multiple modalities and storing data in the server. This software manages, searches and views the stored images in the server. Xmaru PACS is capable of communicating with electronic medical records systems, hospital information systems, and radiology information system via DICOM standard.



Note) XmaruView V1 Naming Rules

Function Model name	Basic	Chiropractic mode	Podiatry mode
XmaruView V1	O	X	X
Xmaru Chiroview	O	O	X
Xmaru Podview	O	X	O

3. Indication for use

XmaruView V1(Xmaru Chiroview or Xmaru Podview) software carries out the image processing and administration of medical X-ray data which includes adjustment of window leveling, rotation, zoom, and measurements. XmaruView V1(Xmaru Chiroview or Xmaru Podview) is not approved for mammography and is meant to be used by qualified medical personnel only. XmaruView V1(Xmaru Chiroview or Xmaru Podview) is complying with DICOM standards to assure optimum communications between network systems.

Xmaru PACS receives, stores, searches and views the diagnostic image data from imaging modalities in DICOM compliant. Xmaru PACS is capable of communicating with electronic medical records systems, hospital information systems, and radiology information system via DICOM standard.

XmaruView V1(Xmaru Chiroview or Xmaru Podview) and Xmaru PACS can be packaged together or offered as a stand-alone imaging solution to be installed in a PC for trained medical professionals.

4. The Main Functions of XmaruView V1(Xmaru Chiroview or Xmaru Podview) and Xmaru PACS

The major functions of XmaruView V1(Xmaru Chiroview or Xmaru Podview) are as follows.

- Automatic acquisition of patient information and photo-taking when taking a shot through the DICOM Worklist.
- Auto Query that searches the Worklist server at every designated interval, facilitating to handle newly added works rapidly and efficiently.
- Display an acquired image within a very short period of time after taking an image.

- Reduce input time for patient information by automatically applying the preset Image Processing Parameter, ROI, Marker, LUT etc. according to different body parts.
- Enables a user to take images simultaneously while conducting a variety of functions, including DICOM image transmission, printing, and Worklist search.
- Provides a variety of image editing functions, including Contrast, Invert, Flip, Rotate, ROI, and Windowing.
- Enable a user to edit images upon acquisition
- Image management functions: test creation, modify and delete of information, move and delete of image, and image storage management.
- Supports DICOM 3.0 and image transmission to the PACS server, print and worklists.
- Chiropractic mode, Podiatry mode

The major functions of Xmaru PACS are as follows.

- Adjust images in real time through searching functions of acquired images
- Perform DICOM image sending and printing
- Provide various image processing functions such as contrast, invert, flip, rotate, ROI, windowing
- Perform image searching, transferring, deleting, managing storage capacity easily
- Perform image sending to PACS, printing and Worklist because DICOM 3.0 is supported
- Provide Server and Client mode

5. Predicate device

Manufacturer : VATECH Co.,Ltd.

Device : XmaruView V1

510(k) Number : K102078 (Decision Date – AUG 10, 2011)

Characteristic	Proposed Rayence Co.,Ltd. XmaruView V1, Xmaru Chiroview, Xmaru Podview and Xmaru PACS	Predicate VATECH Co.,Ltd. XmaruView V1
	* Rayence Co., Ltd – May, 2011 (Separated from Vatech Co., Ltd. as an Independent Affiliate Company)	
510(k) number		K102078 Decision Date – AUG. 10, 2011

Characteristic	Proposed Rayence Co.,Ltd. XmaruView V1, Xmaru Chiroview, Xmaru Podview and Xmaru PACS	Predicate VATECH Co.,Ltd. XmaruView V1
Processor	Intel® Core™ i3 or higher	Intel Core Duo/Core 2 Duo Core Processor
RAM	4GB or higher	min. 1GByte RAM
Hard Disk	min. 80GByte	min. 80GByte
Network	100MBit or 1GBit	100MBit or 1GBit
Operation Software	Microsoft Windows 7(32 bit / 64 bit) Professional Microsoft Windows 8 Professional or Enterprise	Windows XP
Resolution	min. 1280 x 768	1280 x 1024
X-ray Generator Control	XmaruView V1(Xmaru Chiroview or Xmaru Podview) – Yes Xmaru PACS - No	Yes
Image Processing	Yes (same with the predicate device)	Yes
Windowing	Yes	Yes
Image Formatting	Yes (1x1,1x2,2x1,2x2,3x3)	Yes (1x1,1x2,2x1,2x2,3x3)
Electronic zoom	Yes	Yes
Image rotation	Yes	Yes
DICOM Worklist	Yes	Yes
DICOM Store	Yes	Yes

Characteristic	Proposed Rayence Co.,Ltd. XmaruView V1, Xmaru Chiroview, Xmaru Podview and Xmaru PACS	Predicate VATECH Co.,Ltd. XmaruView V1
<i>DICOM Print</i>	Yes	Yes
<i>SW Ver.</i>	XmaruView V1(Xmaru Chiroview or Xmaru Podview) - 2.0 Xmaru PACS - 1.0	XmaruView V1 - 1.0
<i>Added Functions</i>	XmaruView V1(Xmaru Chiroview or Xmaru Podview) - 2.0 1. Add features - Auto Stitching 2. Improve features - Change Image Processing Tab - GPR parameter selectable 3. Added mode - Chiropractic mode - Podiatry mode 4. XmaruView V1 divided the model name. - XmaruView V1 - Xmaru Chiroview - Xmaru Podview Xmaru PACS - 1.0 1. Store SCP : Ability to receive images transmitted from modalities 2. Available Modality Image Display DX, CR, CT, MR, MG, US and PET image modalities	

6. Substantial Equivalence

The subject device and predicate device are substantially equivalent, having the same/similar indications for use and functionalities like operation software, resolution, X-ray generator control, image processing, windowing, zoom, rotation, DICOM worklist, DICOM store and DICOM print. Both subject device and predicate devices are categorized in product code

LLZ; equivalence between these models is evident.

1. The pre / post image processing algorithm is the same for XmaruView V1(ver 1.0) and XmaruView V1(ver 2.0).

2. The differences between XmaruView V1 (ver 1.0) and XmaruView V1 (ver 2.0) are as follows:
 - 1). Add features
 - Auto Stitching
 - 2). Improve features
 - Change Image Processing Tab
 - Selectable GPR parameter
 - 3). Added mode
 - Chiropractic mode
 - Podiatry mode
 - 4). XmaruView V1 divided into different model names.
 - XmaruView V1
 - Xmaru Chiroview
 - Xmaru Podview

The SW Validation, hazard analysis and FMEA, modality validation and functional test were conducted for the software features which are added or changed from XmaruView V1 (ver 1.0), the previous version. The risks identified have been mitigated and any residual risks were evaluated and accepted for XmaruView V1 (ver 2.0).

3. Chiropractic mode and Podiatry mode in XmaruView V1 (ver 2.0) are additional features for XmaruView V1 (ver 2.0). However, they are similar to the measurement function of length and angle already incorporated in XmaruView V1 (Ver 1.0) For the user convenience, a specific region of interest for chiropractic and podiatry was designated as a dedicated mode in XmaruView V1 (ver 2.0).

7.Summary of Performance Testing

Nonclinical Testing:

The complete system configuration has been assessed and tested by the manufacturer and passed all in-house testing criteria. The software validation test was designed to evaluate all input functions, output functions, and actions performed by XmaruView V1(Xmaru Chiroview or Xmaru Podview) and Xmaru PACS. Each operational mode and the process followed are documented in the Software Validation Report.

The validation testing verified and validated the risk analysis and individual performance results were within the predetermined acceptance criteria.

Safety and Performance Data:

- IEC 62304 Medical device software – Software life-cycle processes : 2006
- ISO 14971 Medical Devices – Application of risk management to medical device : 2007
- NEMAPS 3.1-3.20 – Digital Imaging and Communications in Medicine (DICOM) Set (Radiology)

8. Conclusions

None of the modifications alter the Indications for Use in a significant way, nor the fundamental scientific technology, and do not introduce a fundamentally new scientific technology. Therefore, it is our opinion that the XmaruView V1(Xmaru Chiroview or Xmaru Podview) described in this submission is substantially equivalent to the predicate device.