DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

December 8, 2016

iRay Technology (Shanghai) Ltd.
% Mr. Wei Pan
Registration & Regulatory Affairs Manager
Room 202, Building 7, No. 590, Ruiqing Road
Shanghai, 201201
CHINA

Re: K161730
Trade/Device Name: Wireless Digital Flat Panel Detector
Regulation Number: 21 CFR 892.1680
Regulation Name: Stationary x-ray system
Regulatory Class: II
Product Code: MQB
Dated: November 11, 2016
Received: November 18, 2016

Dear Mr. Pan:

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,

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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*

K161730

Device Name
Wireless Digital Flat Panel Detector

Indications for Use *(Describe)*

Mars1417V-PSI Wireless Digital Flat Panel Detector is indicated for digital imaging solution designed for providing general radiographic diagnosis of human anatomy. It is intended to replace radiographic film/screen systems in all general-purpose diagnostic procedures. This device is not intended for mammography or dental applications.

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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SECTION 7

510 (k) SUMMARY OF SAFETY AND EFFECTIVENESS

510 (k) SUMMARY OF SAFETY AND EFFECTIVENESS

(As Required by 21 CFR 807.92)

1. **Date Prepared [21 CFR 807.92(a)(1)]**

   October 19, 2015

2. **Submitter;s Information [21 CFR 807.92(a)(1)]**

Company Name:	iRay Technology (Shanghai) Ltd.
Company Address:	RM 202, Building 7, No. 590, Ruiqing RD., Zhangjiang East, Pudong, Shanghai, China 201201
Contact Person:	Mr. Wei Pan
Phone:	+86 021-50720560
Fax:	+86 021-50720561
Email:	wei.pan@iraychina.com

3. **Trade Name, Common Name, Classification [21 CFR 807.92(a)(2)]**

Trade Name:	Wireless Digital Flat Panel Detector
Common Name:	Flat Panel Detector
Model Name:	Mars1417V-PSI
Classification Name:	Stationary X-Ray System
Product Code:	MQB
Regulation Number:	21 CFR 892.1680
Device Class:	Class II

4. **Identification of Predicate Devices(s) [21 CFR 807.92(a)(3)]**

The identification predicates within this submission are as follows:

Manufacturer:	Viztek LLC
Trade Name:	ViZion DR + Wireless
Model Name:	ViZion DR + Wireless
Product Code:	MQB

Classification Name:	Stationary X-Ray System
FDA 510 (k) #:	K152279

5. Description of the Device [21 CFR 807.92(a)(4)]

Mars1417V-PSI Wireless Digital Flat Panel Detector is a kind of wireless digital flat panel detector. It supports the single frame mode, with the key component of TFT/PD image sensor flat panel of active area: 36cm×43cm.

The sensor plate of Mars1417V-PSI Wireless Digital Flat Panel Detector is direct-deposited with Gd_2O_2S scintillator to achieve the conversion from X-ray to visible photon. The visible photons are transformed to electron signals by diode capacitor array within TFT panel, which are composed and processed by connecting to scanning and readout electronics, consequently to form a panel image by transmitting to PC through the user interface.

The major function of the Mars1417V-PSI Wireless Digital Flat Panel Detector is to convert the X-ray to digital image, with the application of high resolution X-ray imaging. This detector is the key component of DR system, enables to complete the digitalization of the medical X-ray imaging with the DR system software.

The iRay DR used for getting Digital X -ray radiography images from the flat panel detectors. iRay DR is used to handle the DICOM protocol (DICOM 3.0), iRay DR is responsible for the DR equipment management, acquisition and processing functions, to provide patient registration, scanning, image processing and forwarding, and other functions..

6. Intended Use [21 CFR 807.92(a)(5)]

6.1. Intended Use

Mars1417V-PSI Wireless Digital Flat Panel Detector is indicated for digital imaging solution designed for providing general radiographic diagnosis of human anatomy. It is intended to replace radiographic film/screen systems in all general-purpose diagnostic procedures. This device is not intended for mammography or dental applications.

6.2. Suitable patient

It is suitable for providing digital X-ray imaging for DR system conventional photography but not intended for mammography or dental applications. The remaining notes depend on the DR system.

6.3. Processing of input and output

When FPD works continuously, it can automatically distinguish X-ray and output an imaging for diagnosis of disease, injury, or of any applicable health problem

7. Technological Characteristic [21 CFR 807.92(a)(6)]

Item	Proposed Device: Wireless Digital Flat Panel Detector	Predicate Device: ViZion DR + Wireless
510(K) Number	To be assigned	K152279
Intended Use	The Mars1417V-PSI Wireless Digital Flat Panel Detector is indicated for digital imaging solution designed for providing general radiographic system in all general purpose diagnostic procedures.	ViZion DR + Wireless is intended for digital image capture use in general radiographic examinations, wherever conventional screen-film systems may be used, excluding fluoroscopy, angiography and mammography.
Classification Name	Stationary X-ray system	Stationary X-ray system
Product Code	MQB	MQB
Regulation Number	21 CFR 892.1680	21 CFR 892.1680
Panel:	Radiology	Radiology
Classification:	II	II
X-Ray Absorber (Scintillator):	Gd_2O_2S	Gd_2O_2S
Installation Type:	Wireless, Portable	Wireless, Portable
Readout Mechanism:	Thin Film Transistor	Thin Film Transistor
Image Matrix Size:	2304 × 2800 pixels	2304 × 2800 pixels
Pixel Pitch:	150μm	150μm
ADC Digitization	14 bit	14 bit

Item	Proposed Device: Wireless Digital Flat Panel Detector	Predicate Device: ViZion DR + Wireless
Effective Imaging Area:	355 mm × 434 mm	355 mm × 434 mm
Spatial Resolution:	Min. 3.4lp/mm	Min. 3.4lp/mm
Modulation Transfer Function (MTF)	0.75 at 0.5lp/mm	0.75 at 0.5 lp/mm
Detective Quantum Efficiency (DQE)	0.27 at 0.5 lp/mm (RQA5, 3.2μGy)	0.27 at 0.5 lp/mm (RQA5, 3.2μGy)
Power Consumption:	Max. 13W	Max. 13W
Software	Outputs a DICOM image.	Outputs a DICOM image.
DICOM 3	Yes	Yes
Communications:	Wired: Gigabit Ethernet (1000BASE-T) Wireless: IEEE 802.11a/b/g/n (2.4 GHz / 5 GHz)	Wired: Gigabit Ethernet (1000BASE-T) Wireless: IEEE 802.11a/b/g/n (2.4 GHz / 5 GHz)
Imaging protect Plate:	Carbon Fiber Plate	Carbon Fiber Plate
Cooling:	Air cooling	Air cooling
Dimensions:	384 mm × 460 mm × 15 mm	384 mm × 460 mm × 15 mm
Operation:	Temperature: +5 ~ +35℃ Humidity: 30 ~ 75% (Non-Condensing) Atmospheric pressure: 70 ~ 106 kPa Altitude: Max. 3000 meters	Temperature: +5 ~ +35℃ Humidity: 30 ~ 75% (Non-Condensing) Atmospheric pressure: 70 ~ 106 kPa Altitude: Max. 3000 meters

Item	Proposed Device: Wireless Digital Flat Panel Detector	Predicate Device: ViZion DR + Wireless
Storage and Transportation:	Temperature: -20 ~ +55℃ Humidity: 10 ~ 90% (Non-Condensing) Atmospheric pressure: 70 ~ 106 kPa Altitude: Max. 3000 meters	Temperature: -20 ~ +55℃ Humidity: 10 ~ 90% (Non-Condensing) Atmospheric pressure: 70 ~ 106 kPa Altitude: Max. 3000 meters
Software	iRay DR The iRay DR used for getting Digital X -ray radiography images from the flat panel detectors. iRay DR is used to handle the DICOM protocol (DICOM 3.0), iRay DR is responsible for the DR equipment management, acquisition and processing functions, to provide patient registration, scanning, image processing, image forwarding, image printing and other functions.	Opal-RAD™ (k063337) Opal - RAID is a software suite of web based PACS applications that was developed specifically to handle the DICOM protocol, for both transmitting and viewing DICOM images and data elements. The applications were developed so that access to the PACS can occur from any Microsoft Windows computer with internet capabilities, and offer an interface that users find to be quite intuitive after some initial learning. The Opal-RAID applications deal with all manner of DICOM images These images can be viewed, manipulated, annotated, transmitted to other facilities, printed, animated and stored using the Opal-RAID suite. The system does not produce any original medical images.

8. **System requirements to operate with other radiographic system components**

1) Recommended Generator Specification:
Energy range: 40~150kVp
mA range: 10~1000mA (depending on the generator power)
ms range: 10~6300ms to produce 0.1~1000mAs (depending on the generator power)
Note: To our best knowledge, the detector is compatible with the X-ray generators with the specifications described above. If you have any questions regarding the compatibility issue for other generators, please contact your distributor or iRay's service office.

2) Application Program Interface (API) for system integration manufacturer
Peripheral hardware: Mars1417V-PSI detector connected via wireless or wired communication.

Operating System:	Windows XP/7 32/64bit
CPU:	Intel Core i73.6G
Memory:	4G DDR3
Hard Disk:	640 G
LAN Card:	Intel Pro EXP9301CT PRO Gigabit Network Adapter with PCIe interface

3) X-ray exposure mode
The inner trigger module is a unit can connect X-ray signal in the Mars1417V-PSI. Once there is X-ray generator exposure exist, the inner trigger module will detect the X-ray radiation and output signal to the detector. Until the exposure finished, the detector will receive a signal which represent the end of exposure from the inner trigger module and begin to acquire the image.

9. Substantial Equivalence [21 CFR 807.92(b)(1) and 807.92(b)(2)]

1) Electrical Safety and EMC testing:
Electrical, mechanical, environmental safety and performance testing according to IEC/ES 60601-1 was performed, and EMC testing was also conducted in accordance with IEC/EN 60601-1-2. All test results are meet standard requirements.

2) Biological Evaluation:

The materials of the detector which contact operators' skin have been evaluated with the ISO 10993-1. And the evaluation results and test result assured the safety the same as the predicate device.

3) Nonclinical Considerations:

The non-clinical studies have been performed and the results have shown that the Mars1417V-PSI wireless digital X-ray flat panel detector is substantially equivalent to the predicate devices on the Market (ViZion DR+Wireless, K152279):

Detective quantum efficiency (DQE), Quantum limited performance, Modulation transfer function (MTF), Effects of aliasing, Sensitivity linearity, Lag, Change in detection sensitivity, Dose requirement and reciprocity changes, Stability of device characteristics with time, Uniformity of device characteristic, Noise power spectrum(NPS), Spatial resolution, Image Acquisition time, & Black level.

According to the Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices, the software iRayDR classifies the hazards, defines requirements specification and design specification, all the specification pass the 83 test cases and complies the intended design specification.

4) Clinical Consideration:

A concurrence study of 30 clinical images was conducted to compare the performance of the Mars1417V-PSI to that of the predicate device (ViZion DR+Wireless,K152279).

Clinical images were provided; these images were not necessary to establish substantial equivalence based on the differences from the predicate but they provide further evidence in addition to the laboratory performance data to show that the complete system works as intended.

There was no significant difference between the images of the Mars1417V-PSI and those of the predicate device.

10. Conclusion [21 CFR 807.92(b)(3)]

In accordance with the Federal Food, Drug and Cosmetic Act, 21 CFR Part 807 and based on the information provided in this premarket notification, iRay Technology (Shanghai) Ltd. Concludes that iRay Mars1417V-PSI Wireless Digital Flat Panel Detectors is substantially equivalent to predicate device with regards to safety and effectiveness.