iRay Technology Taicang Ltd.
Meng Li
Registration and Regulatory Affairs Engineer
No. 33 Xinggang Rd., Taicang Port Economic & Technological Development Zone
TAICANG, JIANGSU 215434 CN

October 17, 2018

Re: K182550
Trade/Device Name: Wireless Digital Flat Panel Detector
Regulation Number: 21 CFR 892.1680
Regulation Name: Stationary x-ray system
Regulatory Class: Class II
Product Code: MQB
Dated: September 13, 2018
Received: September 17, 2018

Dear Meng Li:

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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 comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

For

Robert A. 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*

K182550

Device Name
Wireless Digital Flat Panel Detector

Indications for Use *(Describe)*

Mars1417XF-GSI 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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510 (k) SUMMARY OF SAFETY AND EFFECTIVENESS

(As Required by 21 CFR 807.92)

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

August 1st, 2018

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

Company Name:	iRay Technology Taicang Ltd.
Company Address:	No.33 Xinggang Road, Taicang Port Economic and Technological Development Zone, Jiangsu, China 215434
Contact Person:	Meng Li
Phone:	0512-53690872
Fax:	0512-53690872
Email:	meng.li@iraychina.com

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

Trade Name:	Wireless Digital Flat Panel Detector
Common Name:	Solid State X-Ray Imager
Model Name:	Mars1417XF-GSI
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: iRay Technology Co.,Ltd.

Trade Name:	Wireless Digital Flat Panel Detector
Model Name:	Mars1417V-PSI
Product Code:	MQB
Classification Name:	Stationary X-Ray System
FDA 510 (k) #:	K161730

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

Mars1417XF-GSI 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: 35.04cm×42.54cm.

The sensor plate of Mars1417XF-GSI 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 Mars1417XF-GSI 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.

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

6.1. Intended Use

Mars1417XF-GSI 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 flat panel detector 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	Predicate Device: Wireless Digital Flat Panel Detector	Proposed Device: Wireless Digital Flat Panel Detector
510(K) Number	K161730	To be assigned
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.	Same
Classification Name	Stationary X-ray system	Same
Product Code	MQB	Same
Regulation Number	21 CFR 892.1680	Same

Item	Predicate Device: Wireless Digital Flat Panel Detector	Proposed Device: Wireless Digital Flat Panel Detector
Panel:	Radiology	Same
Classification:	II	Same
X-Ray Absorber (Scintillator):	Gd_2O_2S	Same
Installation Type:	Wireless, Portable	Same
Readout Mechanism:	Thin Film Transistor	Same
Image Matrix Size:	2304 × 2800 pixels	2336× 2836 pixels
Pixel Pitch:	150μm	Same
ADC Digitization	14 bit	16 bit
Effective Imaging Area:	355 mm × 434 mm	350.4 mm × 425.4 mm
Spatial Resolution:	Min. 3.4lp/mm	Min. 3.3lp/mm
Modulation Transfer Function (MTF)	0.75 at 0.5lp/mm	0.84 at 1 lp/mm
Detective Quantum Efficiency (DQE)	0.27 at 0.5 lp/mm (RQA5, 3.2μGy)	0.43 at 1 lp/mm (RQA5, 2.5μGy)
Power Consumption:	Max. 13W	Max. 19W

Item	Predicate Device: Wireless Digital Flat Panel Detector	Proposed Device: Wireless Digital Flat Panel Detector
Communications:	Wired: Gigabit Ethernet (1000BASE-T) Wireless: IEEE 802.11a/b/g/n (2.4 GHz / 5 GHz)	Wireless: IEEE 802.11a/b/g/n (2.4 GHz / 5 GHz)
Imaging protect Plate:	Carbon Fiber Plate	Same
Cooling:	Air cooling	Same
Dimensions:	384 mm × 460 mm × 15 mm	Same
Operation:	Temperature: +5 ~ +35℃ Humidity: 30 ~ 75% (Non-Condensing) Atmospheric pressure: 70 ~ 106 kPa Altitude: Max. 3000 meters	Temperature: +5 ~ +30℃ Humidity: 10 ~ 80% (Non-Condensing) Atmospheric pressure: 70 ~ 106 kPa Altitude: Max. 3000 meters
Storage and Transportation:（detector）	Temperature: -20 ~ +55℃ Humidity: 10 ~ 90% (Non-Condensing) Atmospheric pressure: 70 ~ 106 kPa Altitude: Max. 3000 meters	Temperature: -20 ~ +50℃ 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	iRay SDK(include iDetector) is intend to supply API interface for

Item	Predicate Device: Wireless Digital Flat Panel Detector	Proposed Device: Wireless Digital Flat Panel Detector
	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.	DR system manufacturers. DR system manufacturer control the detector by SDK interface. SDK is not intend to use directly by other users beside DR system manufacturers.

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: Mars1417XF-GSI detector connected via wireless communication.

Operating System:	Windows XP/7 32/64bit
CPU:	Intel Core i5 3.6G
Memory:	8G DDR3
Hard Disk:	640 G
LAN Card:	Intel Pro EXP9301CT PRO Gigabit Network Adapter with PCIe interface

3) X-ray exposure mode

The AED trigger module is a unit can connect X-ray signal in the Mars1417XF-GSI. 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 60601-1-2. All test results are meet the standard requirements.

2) Biological Evaluation:

The materials of the detector which contact operators' or patient's 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 Mars1417XF-GSI wireless digital X-ray flat panel detector is substantially equivalent to the predicate devices on the Market (Mars1417V-PSI, K161730):

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, and Black level. According to the Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices, the software SDK classifies the hazards, defines requirements specification and design specification, all the specification pass the 16 test cases and complies the intended design specification.

4) Clinical Consideration:

Nonclinical information of Mars1417XF-GSI is sufficient to support the substantial equivalence of a subject to a predicate device (Mars1417V-PSI, K161730) for its modifications without the need to provide additional clinical data.

The only change for the Mars1417XF-GSI is in the ADC Digitization and software. And for the communication function, the Mars1417XF-GSI reduce the wired communication function.

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 Taicang Ltd. Concludes that iRay Mars1417XF-GSI Wireless Digital Flat Panel Detectors is substantially equivalent to predicate device with regards to safety and effectiveness.