



iRay Technology Taicang Ltd.
% Meng Li
Registration & Regulation Affairs Engineer
No. 33 Xinggang Rd., Taicang Port Economic &
Technological Development Zone
Taicang, Jiangsu 215434
CHINA

January 9, 2019

Re: K183422
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: November 1, 2018
Received: December 10, 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,

A handwritten signature in blue ink that reads "Michael D. O'Hara". The signature is written over a large, semi-transparent blue "FDA" logo.

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)

K183422

Device Name

Wireless Digital Flat Panel Detector

Indications for Use (Describe)

Mars1717XF-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.

We understand the Agency has become aware of situations where solid state detectors inserted into radiographic systems adversely impacted device performance due to improper integration (reference:<http://www.fda.gov/downloads/MedicalDevices/ResourcesforYou/Industry/UCM385149.pdf>).

Below is a summary of the information from the Mars1717XF-GSI user manuals covering key electromechanical and computer requirements needed for X-ray system interface and integration.

1. Mechanical interface requirements.
2. Computer requirements
3. Data communication interface requirements
4. Electrical power requirements
5. X-ray trigger interface requirements

Neither the Mars1717XF-GSI detector nor its software act as an X-ray generator controller, and therefore, the device is not subject to Electronic Product Radiation Control (EPRC) performance standards and reporting requirements.

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)]

November 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
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Email: meng.li@iraygroup.com

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

510(k) Number: K183422
Trade Name: Wireless Digital Flat Panel Detector
Common Name: Solid State X-Ray Imager
Model Name: Mars1717XF-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:

<u>Manufacturer:</u>	iRay Technology Taicang Ltd.
<u>Trade Name:</u>	Wireless Digital Flat Panel Detector
<u>Model Name:</u>	Mars1417XF-GSI
<u>Product Code:</u>	MQB
<u>Classification Name:</u>	Stationary X-Ray System
<u>FDA 510 (k) #:</u>	K182550

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

Mars1717XF-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 (Thin Film Transistor)/PD (Photo Diode) image sensor flat panel of active area: 42.48cm×42.54cm.

The sensor plate of Mars1717XF-GSI Wireless Digital Flat Panel Detector is coated with Gd₂O₂S (GOS) 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 Mars1717XF-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**

Mars1717XF-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, dental applications, pediatric, pregnant women and fluoroscopy.

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	K182550	To be assigned
Intended Use	The Mars1417XF-GSI Wireless Digital Flat Panel Detector is indicated for digital imaging solution designed for providing general radiographic system in all general purpose diagnostic procedures.	Same with Mars1417XF-GSI, additionally, it is not intended for mammography, dental

<p>Item</p>	<p>Predicate Device: Wireless Digital Flat Panel Detector</p>	<p>Proposed Device: Wireless Digital Flat Panel Detector</p>
		<p>applications, pediatric, pregnant women and fluoroscopy.</p>
<p>Indications for Use</p>	<p>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.</p> <p>We understand the Agency has become aware of situations where solid state detectors inserted into radiographic systems adversely impacted device performance due to improper integration (reference:http://www.fda.gov/downloads/MedicalDevices/ResourcesforYou/Industry/UCM385149.pdf).</p>	<p>Same with Mars1417XF-GSI, additionally, In the consideration of patient size (i.e., height, weight, body part thickness) and usable dose range, the detector could be used for general X ray diagnosis of usual body part for adult.</p>

Item	<p>Predicate Device: Wireless Digital Flat Panel Detector</p>	<p>Proposed Device: Wireless Digital Flat Panel Detector</p>
	<p>Below is a summary of the information from the Mars1417XF-GSI user manuals covering key electromechanical and computer requirements needed for X-ray system interface and integration.</p> <ol style="list-style-type: none"> 1. Mechanical interface requirements. 2. Computer requirements 3. Data communication interface requirements 4. Electrical power requirements 5. X-ray trigger interface requirements <p>Neither the Mars1417XF-GSI detector nor its software act as an X-ray generator controller, and therefore, the device is not subject to Electronic Product Radiation Control (EPRC) performance standards and reporting requirements.</p>	
Classification Name	Stationary X-ray system	Same

Item	Predicate Device: Wireless Digital Flat Panel Detector	Proposed Device: Wireless Digital Flat Panel Detector
Product Code	MQB	Same
Regulation Number	21 CFR 892.1680	Same
Panel:	Radiology	Same
Classification:	II	Same
X-Ray Absorber (Scintillator):	Gd ₂ O ₂ S (GOS)	Same
Installation Type:	Wireless, Portable	Same
Readout Mechanism:	Thin Film Transistor	Same
Image Matrix Size:	2336 × 2836 pixels	2832 × 2836 pixels
Pixel Pitch:	150μm	Same
ADC Digitization	16 bit	Same
Effective Imaging Area:	350.4 mm × 425.4 mm	424.8 mm × 425.4 mm
Spatial Resolution:	Min. 3.3lp/mm	Same
Modulation Transfer Function (MTF)	0.45 at 1 lp/mm	0.44 at 1 lp/mm
Detective Quantum Efficiency	0.22 at 1 lp/mm	0.23 at 1 lp/mm

Item	Predicate Device: Wireless Digital Flat Panel Detector	Proposed Device: Wireless Digital Flat Panel Detector
(DQE) (RQA5, 3.2 μ Gy)		
Power Consumption:	Max. 19W	Max. 20W
Communications: (Wireless functionality)	Wireless: IEEE 802.11a/b/g/n (2.4 GHz / 5 GHz)	Same
Communications:	Wireless: IEEE 802.11a/b/g/n (2.4 GHz / 5 GHz)	Same
Imaging protect Plate:	Carbon Fiber Plate	Same
Cooling:	Air cooling	Same
Dimensions:	384 mm \times 460 mm \times 15 mm	460 mm \times 460 mm \times 15 mm
Operation:	Temperature: +5 ~ +30 $^{\circ}$ C Humidity: 10 ~ 80% (Non-Condensing) Atmospheric pressure: 70 ~ 106 kPa Altitude: Max. 3000 meters	Same
Storage and Transportation: (detector)	Temperature: -20 ~ +50 $^{\circ}$ C Humidity: 10 ~ 90% (Non-Condensing)	Same

Item	Predicate Device: Wireless Digital Flat Panel Detector	Proposed Device: Wireless Digital Flat Panel Detector
	Atmospheric pressure: 70 ~ 106 kPa Altitude: Max. 3000 meters	
Software	iRay SDK(include iDetector) is intend to supply API interface for 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.	Same
Utilized FDA guidance documents	<ol style="list-style-type: none"> 1. Guidance for the Submission of 510(k)'s for Solid State X-ray Imaging Devices; 2. The 510(k) Program: Evaluating Substantial Equivalence in Premarket Notifications[510(k)]; 3. Content of Premarket Submissions for Management of Cybersecurity in Medical Devices; 4. Radio Frequency Wireless Technology in Medical Devices. 	Same

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 still having any questions regarding the compatibility issue for other generators, please contact the distributor or iRay's service office.

2) Application Program Interface (API) for system integration manufacturer

Peripheral hardware: Mars1717XF-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 Mars1717XF-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/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) Non-clinical Considerations:

The only modification from the predicate device to Mars1717XF-GSI is the panel dimension, related to Amorphous Silicon (A-Si) panel size and structure size design. The non-clinical studies have been performed and the results have shown that sections of the non-clinical consideration mentioned in the 'Guidance for the Submission of 510(k)s for Solid State X-ray Imaging Devices' are substantially equivalent to the non-consideration of predicate devices on the Market (Mars1417XF-GSI, K182550).

4) Clinical Consideration:

The only modification from the predicate device to Mars1717XF-GSI is the panel dimension, related to Amorphous Silicon (a-Si) panel size and structure size design. Intended use, fundamental scientific technology, regulatory requirement, non-clinical performance, labeling, quality-assurance program and software keep the same with those of predicate device. Additionally, as mentioned in clinical considerations in 'Guidance for the Submission of 510(k)s for Solid State X-ray Imaging Devices', clinical consideration may not necessary for changes in the dimensions of the image receptor with otherwise identical materials if non-clinical information is sufficient to support the substantial equivalence, which is described details in '009_Substantial Equivalence Discussion' in this submission.

There was no significant difference between the images of the Mars1717XF-GSI 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 Taicang Ltd. concludes that iRay Mars1717XF-GSI Wireless Digital Flat Panel Detectors is substantially equivalent to predicate device with regards to safety and effectiveness.