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

May 1, 2020

Re: K201004
Trade/Device Name: Wireless Digital Flat Panel Detector (Models, Mars1417V-TSI, Mano4336W)
Regulation Number: 21 CFR 892.1680
Regulation Name: Stationary x-ray system
Regulatory Class: Class II
Product Code: MQB
Dated: April 10, 2020
Received: April 23, 2020

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/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); 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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). 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 (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-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

Thalia T. Mills, Ph.D.
Director
Division of Radiological Health
OHT7: Office of In Vitro Diagnostics
and Radiological Health
Office of Product Evaluation and Quality
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)*

K201004

Device Name
Wireless Digital Flat Panel Detector

Indications for Use *(Describe)*

Mars1417V-TSI wireless digital flat panel detector and Mano4336W wireless digital flat panel detector are indicated for digital imaging solutions designed to provide general radiographic diagnosis for human anatomy including both adult and pediatric patients. They are intended to replace film/screen systems in all general–purpose diagnostic procedures. The 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.

510 (k) SUMMARY OF SAFETY AND EFFECTIVENESS

(As Required by 21 CFR 807.92) K201004

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

April 29th, 2020

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
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Email:	meng.li@iraygroup.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:	Mars1417V-TSI Mano4336W
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 Taicang Ltd.
Trade Name:	Wireless Digital Flat Panel Detector
Model Name:	Mars1417XF-CSI
Product Code:	MQB
Classification Name:	Stationary X-Ray System
Regulation Number:	21 CFR 892.1680
Device Class:	Class II
FDA 510 (k) #:	K182551

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

Mars1417V-TSI and Mano4336W Wireless Digital Flat Panel Detectors (Hereinafter referred to as Mars1417V-TSI and Mano4336W) are the kind of wireless digital flat panel detectors. They support the single frame mode, with the key component of TFT/PD image sensor flat panel of active area: 34.56cm×42.00cm. Mars1417V-TSI and Mano4336W are totally same except for label and model name.

The sensor plate of Mars1417V-TSI and Mano4336W is direct-deposited with CsI 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-TSI and Mano4336W is to convert the X-ray to digital image, with the application of high resolution X-ray imaging. Both kinds of detectors are the key component of DR system, enable to complete the digitalization of the medical X-ray imaging with the DR system 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 be used directly by other users beside DR system manufacturers.

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

6.1. Indications for use

Mars1417V-TSI wireless digital flat panel detector and Mano4336W wireless digital flat panel detector are indicated for digital imaging solutions designed to provide general radiographic diagnosis for human anatomy including both adult and pediatric patients. They are intended to replace film/screen systems in all general–purpose diagnostic procedures. The 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 to provide general radiographic diagnosis for human anatomy including both adult and pediatric patients, 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	K182551	To be assigned
Intended Use	The Mars1417XF-CSI Wireless Digital Flat Panel Detector is indicated for digital imaging solution designed for providing general radiographic	same

Item	Predicate Device: Wireless Digital Flat Panel Detector	Proposed Device: Wireless Digital Flat Panel Detector
	system in all general-purpose diagnostic procedures.	
Indications for Use	The Mars1417XF-CSI Wireless Digital Flat Panel Detector is indicated for digital imaging solution designed for providing general radiographic diagnosis of human anatomy. 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 Mars1417XF-CSI user manuals covering key electromechanical	Same with Mars1417XF-CSI, 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 both adults and pediatric patients.

Item	Predicate Device: Wireless Digital Flat Panel Detector	Proposed Device: Wireless Digital Flat Panel Detector
	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 Mars1417XF-CSI 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.	
Classification Name	Stationary X-ray system	Same
Product Code	MQB	Same
Regulation Number	21 CFR 892.1680	Same
Panel:	Radiology	Same

Item	Predicate Device: Wireless Digital Flat Panel Detector	Proposed Device: Wireless Digital Flat Panel Detector
Classification:	II	Same
X-Ray Absorber (Scintillator):	CsI	Same
Installation Type:	Wireless, Portable	Same
Readout Mechanism:	Thin Film Transistor	Same
Image Matrix Size:	2336× 2836 pixels	2304 × 2800 pixels
Pixel Pitch:	150μm	Same
ADC Digitization	16 bit	Same
Effective Imaging Area:	350.4 mm × 425.4 mm	345.6 mm × 420.0 mm
Spatial Resolution:	Min. 3.3lp/mm	Same
Modulation Transfer Function (MTF)	0.5 at 1 lp/mm	0.68 at 1 lp/mm
Detective Quantum Efficiency (DQE)	0.37 at 1 lp/mm (RQA5, 2.5μGy)	0.36 at 1 lp/mm (RQA5, 2.5μGy)
Power Consumption:	Max. 19W	Max. 18W

Item	Predicate Device: Wireless Digital Flat Panel Detector	Proposed Device: Wireless Digital Flat Panel Detector
Communications: (Wireless functionality)	Wireless: IEEE 802.11a/b/g/n (2.4 GHz / 5 GHz)	a) Wired（only for service）: Gigabit Ethernet (1000BASE-T) b) Wireless: IEEE 802.11a/b/g/n/ac (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 ~ +30℃ Humidity: 10 ~ 80% (Non-Condensing) Atmospheric pressure: 70 ~ 106 kPa Altitude: Max. 3000 meters	Temperature: +5 ~ +35℃ Humidity: 10 ~ 90% (Non-Condensing) Atmospheric pressure: 70 ~ 106 kPa Altitude: Max. 3000 meters
Storage and Transportation:（detector）	Temperature: -20 ~ +50℃ Humidity: 10 ~ 90% (Non-Condensing) Atmospheric pressure: 70 ~ 106 kPa Altitude: Max. 3000 meters	Temperature: -20 ~ +55℃ Humidity: 5 ~ 95% (Non-Condensing) 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	Same

Item	Predicate Device: Wireless Digital Flat Panel Detector	Proposed Device: Wireless Digital Flat Panel Detector
	control the detector by SDK interface. SDK is not intend to use directly by other users beside DR system manufacturers.	
Utilized FDA guidance documents	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 with Mars1417XF-CSI, additionally: 1. Guidance for "Premarket Assessment of Pediatric Medical Devices"; 2. Guidance for "Pediatric Information for X-ray Imaging Device Premarket Notifications".

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 the distributor or iRay's service office.

2) Application Program Interface (API) for system integration manufacturer
Peripheral hardware: Mars1417V-TSI and Mano4336W connected via wireless communication.

Operating System:	Windows 7 32/64bit
CPU:	Intel Core i7 3.6G
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 AED trigger module is a unit can connect X-ray signal in the Mars1417V-TSI/Mano4336W. Once there is X-ray generator exposure exist, the AED 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 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) Non-clinical Considerations:

One modification from the predicate device to Mars1417V-TSI and Mano4336W is geometric design, related to Amorphous Silicon (A-Si) panel size. Another modification is wireless functionality, predicate device has higher wireless transmission speed.

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-CSI, K182551).

4) Clinical Consideration:

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.

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 Mars1417V-TSI and Mano4336W are substantially equivalent to predicate device with regards to safety and effectiveness.