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

April 1, 2020

Re: K200622
Trade/Device Name: Focus 43C Detector, TRIMAX 43C Detector
Regulation Number: 21 CFR 892.1680
Regulation Name: Stationary x-ray system
Regulatory Class: Class II
Product Code: MQB
Dated: February 14, 2020
Received: March 9, 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)*
K200622

Device Name
Focus 43C Detector
TRIMAX 43C Detector

Indications for Use *(Describe)*
Focus 43C and TRIMAX 43C 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. These two devices are not intended for mammography, dental applications
.
There are no differences between the 2 models except the model name and trade mark.

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 6

510 (k) SUMMARY OF SAFETY AND EFFECTIVENESS

510 (k) SUMMARY OF SAFETY AND EFFECTIVENESS
K200622

(As Required by 21 CFR 807.92)

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

Jan. 8th, 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:	Junjie Qian
Phone:	0512-53690872
Fax:	0512-53690872
Email:	junjie.qian@iraygroup.com

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

Trade Name:	Focus 43C Detector TRIMAX 43C Detector
Common Name:	Solid State X-Ray Imager
Model Name:	Focus 43C TRIMAX 43C
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:	Mars1717XF-CSI
Product Code:	MQB
Device Class:	Class II
Classification Name:	Stationary x-ray system
FDA 510 (k) #:	K183713

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

Focus 43C Detector and TRIMAX 43C Detector (Hereinafter referred to as Focus 43C and TRIMAX 43C) are a 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: 427mm x 427mm. Two models TRIMAX 43C and Focus 43C are totally same except for label and trademark.

The sensor plate of Focus 43C and TRIMAX 43C detectors are 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 Focus 43C and TRIMAX 43C detectors are to convert the X-ray to digital image, with the application of high-resolution X-ray imaging. This kind of detector is the key component of DR system, enables 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 intended to be used directly by other users beside DR system manufacturers. The iRay SDK is unchanged from the predicate device.

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

6.1. Indications for use

Focus 43C and TRIMAX 43C 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. This device is not intended for mammography, dental applications. There are no differences between the 2 models except the model name and trade mark.

6.2. Suitable patient

They are 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	K183713	K200622
Intended Use	The Mars1717XF-CSI Wireless Digital Flat Panel Detector is indicated for digital imaging	same

Item	Predicate Device: Wireless Digital Flat Panel Detector	Proposed Device: Wireless Digital Flat Panel Detector
	solution designed for providing general radiographic system in all general-purpose diagnostic procedures.	
Indications for Use	Mars1717XF-CSI 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/Resourc	Same with Mars1717XF-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 adults and pediatric patients. .

Item	Predicate Device: Wireless Digital Flat Panel Detector	Proposed Device: Wireless Digital Flat Panel Detector
	esforYou/Industry/UCM385149.pdf). Below is a summary of the information from the Mars1717XF-CSI 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-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.	

Item	Predicate Device: Wireless Digital Flat Panel Detector	Proposed Device: Wireless Digital Flat Panel Detector
Classification Name	Stationary x-ray system	Same
Product Code	MQB	Same
Regulation Number	21 CFR 892.1680	Same
Panel:	Radiology	Same
Classification:	II	Same
X-Ray Absorber (Scintillator):	CsI	Same
Installation Type:	Wireless, Portable	Same
Readout Mechanism:	Thin Film Transistor	Same
Image Matrix Size:	2832× 2836 pixels	3072 × 3072 pixels
Pixel Pitch:	150μm	139μm
ADC Digitization	16 bit	Same
Effective Imaging Area:	424.8 mm × 425.4 mm	427 mm × 427 mm
Spatial Resolution:	3.3lp/mm	3.6lp/mm
Modulation Transfer Function (MTF)	0.49 at 1 lp/mm	0.61 at 1 lp/mm

Item	Predicate Device: Wireless Digital Flat Panel Detector	Proposed Device: Wireless Digital Flat Panel Detector
Detective Quantum Efficiency (DQE)	0.40 at 1 lp/mm (RQA5, 2.5μGy)	0.46 at 1 lp/mm (RQA5, 2.5μGy)
Power Consumption:	Max. 20W	Max. 20W
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:	460 mm × 460 mm × 15 mm	460 mm × 460 mm × 15.2 mm
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:	Temperature: -20 ~ +50℃ Humidity: 10 ~ 90%	Temperature: -20 ~ +55℃ Humidity: 5 ~ 95%

Item	Predicate Device: Wireless Digital Flat Panel Detector	Proposed Device: Wireless Digital Flat Panel Detector
（detector）	(Non-Condensing) Atmospheric pressure: 70 ~ 106 kPa Altitude: Max. 3000 meters	(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 control the detector by SDK interface. SDK is not intended to use directly by other users beside DR system manufacturers.	Same
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 Mars1717XF-CSI, additionally: Guidance for "Premarket Assessment of Pediatric Medical Devices"; 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: 40~150keV

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: Focus 43C and TRIMAX 43C detectors connected via wireless communication.

Minimum computer hardware requirement is：

- Windows 10 Professional 64 bit
- Intel Core(TM)2 Duo CPU E7400 @ 2.80GHz or equivalent AMD CPU
- 4GB DRAM memory
- 200GB hard disk
- Ethernet card 100 Mbp/s (Dual Ethernet cards required)
- CD/DVD writer
- 17" display of 1280x800 resolution.
- 2 USB ports

3) X-ray exposure mode

The AED trigger module is a unit can connect X-ray signal in the Focus 43C and TRIMAX 43C. 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) Non-clinical Considerations:

One modification from the predicate device to Focus 43C and TRIMAX 43C is geometric design, related to Amorphous Silicon (A-Si) panel size and structure size design. 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 (Mars1717XF-CSI, K183713).

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 pixel size and resolution with the same x-ray detection material and may not necessary for changes in the wireless functionality if non-clinical information is sufficient to support the substantial equivalence.

There was no significant difference between the images of the Focus 43C/TRIMAX 43C 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 Focus 43C and TRIMAX 43C are substantially equivalent to predicate device with regards to safety and effectiveness.