March 29, 2022

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

Re: K213646
Trade/Device Name: Focus HD 35 Detector
Regulation Number: 21 CFR 892.1680
Regulation Name: Stationary x-ray system
Regulatory Class: Class II
Product Code: MQB
Dated: October 20, 2021
Received: November 4, 2021

Dear Junjie Qian:

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,

Laurel Burk, Ph.D.
Assistant Director
Diagnostic X-ray Systems Team
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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K213646

Device Name
Focus HD 35 Detector

Indications for Use *(Describe)*
Focus HD 35 Detector is indicated for digital imaging solutions designed to provide general radiographic diagnosis for human anatomy including both adult and pediatric patients. It is 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.

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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)]

October 13, 2021

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

Trade Name:	Focus HD 35 Detector
Common Name:	Solid State X-Ray Imager
Model Name:	Focus HD 35
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:	Mars1417X
Product Code:	MQB
Classification Name:	Stationary X-Ray System
Regulation Number:	21 CFR 892.1680
Device Class:	Class II
FDA 510 (k) #:	K210316

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

Focus HD 35 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: 35cm×43cm.

The sensor plate of Focus HD 35 Detector 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 Focus HD 35 Detector 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.

SDK(include iDetector) is intended 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

Focus HD 35 Detector is indicated for digital imaging solutions designed to provide general radiographic diagnosis for human anatomy including both adult and pediatric patients. It is 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 Focus HD 35 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: Mars1417X Wireless Digital Flat Panel Detector	Proposed Device: Focus HD 35 Detector
510(K) Number	K210316	
Intended Use	Mars1417X Wireless Digital Flat Panel Detector is indicated for digital imaging solution designed for providing general radiographic system in all general-purpose diagnostic procedures.	same

Item	Predicate Device: Mars1417X Wireless Digital Flat Panel Detector	Proposed Device: Focus HD 35 Detector
Indications for Use	Mars1417X wireless digital flat panel detector is indicated for digital imaging solutions designed to provide general radiographic diagnosis for human anatomy including both adult and pediatric patients. It is intended to replace film/screen systems in all general–purpose diagnostic procedures. The device is not intended for mammography or dental applications.	Same
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:	3500 × 4300 pixels	Same

Item	Predicate Device: Mars1417X Wireless Digital Flat Panel Detector	Proposed Device: Focus HD 35 Detector
Pixel Size:	100μm	Same
ADC Digitization	16 bit	Same
Effective Imaging Area:	350.0 mm × 430.0 mm	Same
Spatial Resolution:	Min. 4.3lp/mm	5.0 lp/mm
Modulation Transfer Function (MTF)	0.65 at 1 lp/mm	Same
Detective Quantum Efficiency (DQE)	0.54 at 1 lp/mm (RQA5, 2.5μGy)	Same
Power Consumption:	Max. 19W	Max.35.5W
Communications: (Wireless functionality)	a) Wired（only for service）: Gigabit Ethernet (1000BASE-T) b) Wireless: IEEE 802.11a/b/g/n/ac (2.4 GHz / 5 GHz)	Same
Imaging protect Plate:	Carbon Fiber Plate	Same
Cooling:	Air cooling	Same
Dimensions:	384 mm × 460 mm × 15 mm	Same

Item	Predicate Device: Mars1417X Wireless Digital Flat Panel Detector	Proposed Device: Focus HD 35 Detector
Detector IP grade	IP56	Same
Power input port	4 pin port	10 pin port
Surface pressure	Uniform load：300 kg over the whole area of the surface; Local load：150 kg on an area 4 cm diameter of center	Uniform load：300 kg over the whole area of the surface; Local load：100 kg on an area 4 cm diameter of center
Operation:	Temperature: +10 ~ +35℃ Humidity: 5 ~ 90% (Non-Condensing) Atmospheric pressure: 70 ~ 106 kPa Altitude: Max. 3000 meters	Temperature: +5 ~ +35℃ Humidity: 5 ~ 90% (Non-Condensing) Atmospheric pressure: 70 ~ 106 kPa Altitude: Max. 3000 meters
Storage and Transportation: （detector）	Temperature: -20 ~ +55℃ Humidity: 5 ~ 95% (Non-Condensing) Atmospheric pressure: 60 ~ 106 kPa Altitude: Max. 3000 meters	Temperature: -20 ~ +55℃ Humidity: 5 ~ 95% (Non-Condensing) Atmospheric pressure: 70 ~ 106 kPa Altitude: Max. 3000 meters
Software	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	Same

Item	Predicate Device: Mars1417X Wireless Digital Flat Panel Detector	Proposed Device: Focus HD 35 Detector
	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; 5. Guidance for "Premarket Assessment of Pediatric Medical Devices"; 6. Guidance for "Pediatric Information for X-ray Imaging Device Premarket Notifications".	Same

Item	Predicate Device: Mars1417X Wireless Digital Flat Panel Detector	Proposed Device: Focus HD 35 Detector
	7. The Special 510(k) Program 8. Design Control Guidance For Medical Device Manufacturers 9. Appropriate Use of Voluntary Consensus Standards in Premarket Submissions for Medical Devices	

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 manufacturer's service office.
2) Application Program Interface (API) for system integration manufacturer
   Minimum configuration: Focus HD 35 Detector connected via wireless communication.

Operating System:	Windows embedded
CPU:	Intel Core i3- 8100 3.6GHz 4C 65W
Memory:	16GB (2x8GB) DDR4 2666 DIMM

Hard Disk: 1TB

3) X-ray exposure mode

The AED trigger module is a unit can connect X-ray signal in the Focus HD 35 Detector. 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:

Main modification from the predicate device is DC input port change（from 4 pin port to 10 pin port）. This DC input port is only designed and applicable for DR system manufacturer.

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-clinical consideration of predicate device on the Market (Mars1417X, K210316).

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. There is no any change about clinical performance from 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 HD 35 Detector is substantially equivalent to predicate device with regards to safety and effectiveness.