June 16, 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: K221345
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: June 13, 2022
Received: June 15, 2022

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
DHT 8B: Division of Radiological Imaging
and Electronic Products
OHT8: Office of 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)*
K221345

Device Name
Wireless Digital Flat Panel Detector

Indications for Use *(Describe)*
Luna1012X 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.

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510 (k) SUMMARY OF SAFETY AND EFFECTIVENESS

(As Required by 21 CFR 807.92)

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

April 7, 2022

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:	Wireless Digital Flat Panel Detector
Common Name:	Solid State X-Ray Imager
Model Name:	Luna1012X
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:	Mars1013X
Product Code:	MQB
Classification Name:	Stationary X-Ray System
Regulation Number:	21 CFR 892.1680
Device Class:	Class II
FDA 510 (k) #:	K220668

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

Luna1012X Wireless Digital Flat Panel Detector (Hereinafter referred to as Luna1012X) is the 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: 31.52cm×25.02cm

The sensor plate of Luna1012X 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 Luna1012X 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 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

Luna1012X 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.

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: Mars1013X Wireless Digital Flat Panel Detector	Proposed Device: Luna1012X Wireless Digital Flat Panel Detector
510(K) Number	K220668	K221345
Intended Use	Mars1013X 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: Mars1013X Wireless Digital Flat Panel Detector	Proposed Device: Luna1012X Wireless Digital Flat Panel Detector
Indications for Use	Mars1013X 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
Sensor martial	Amorphous Silicon TFT Panel	Flexible Amorphous Silicon TFT Panel

Item	Predicate Device: Mars1013X Wireless Digital Flat Panel Detector	Proposed Device: Luna1012X Wireless Digital Flat Panel Detector
Image Matrix Size:	3318 × 2528 pixels	3152×2502 pixels
Pixel Size:	100μm	Same
ADC Digitization	16 bit	Same
Effective Imaging Area:	331.8 mm × 252.8 mm	315.2 mm×250.2 mm
Spatial Resolution:	Min. 4.3lp/mm	Same
Modulation Transfer Function (MTF)	Min. 0.60 at 1 lp/mm	Same
Detective Quantum Efficiency (DQE)	Min. 0.43 at 1 lp/mm (RQA5, 2.5μGy)	Same
Power Consumption:	Max. 18W	Same
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:	362.1mm×269.2mm×15.5mm	362.1mm×269.2mm×15mm

Item	Predicate Device: Mars1013X Wireless Digital Flat Panel Detector	Proposed Device: Luna1012X Wireless Digital Flat Panel Detector
Detector IP grade	IPX5	IP67
Power input	adapter port input : 24Vdc 0.75A Battery port input: 11.55Vdc 1.6A	Same
Surface pressure	Uniform load：150 kg over the whole area of the surface; Local load：100 kg on an area 4 cm diameter of center	Uniform load：300 kg over the whole area of the surface; Local load：150 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	Same
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% RH (Non-Condensing) Atmospheric pressure: 700~1060mbar Altitude: Max. 3000 meters
Software	SDK(include iDetector) is intend to supply API interface for DR system manufacturers. DR system manufacturer	Same

Item	Predicate Device: Mars1013X Wireless Digital Flat Panel Detector	Proposed Device: Luna1012X Wireless Digital Flat Panel Detector
	control the detector by SDK interface. SDK is not intended to use directly by other users beside DR system manufacturers.	
Applicable guidance	Content of Premarket Submissions for Management of Cybersecurity in Medical Devices Guidance for Industry and Food and Drug Administration Staff Document Issued on: October 2, 2014 Pediatric Information for X-ray Imaging Device Premarket Notifications Guidance for Industry and Food and Drug Administration Staff Document issued on November 28, 2017. Guidance for the Submission of 510(k)s for Solid State X-ray Imaging Devices Guidance for Industry and Food and Drug Administration Staff	Same

Item	Predicate Device: Mars1013X Wireless Digital Flat Panel Detector	Proposed Device: Luna1012X Wireless Digital Flat Panel Detector
	Document issued on: September 1, 2016 Guidance for Industry and FDA Staff Guidance for the Content of Premarket Submissions for Software contained in Medical Devices, Document issued on: May 11, 2005 Medical Devices, Document issued on: May 11, 2005 Radio Frequency Wireless Technology in Medical Devices-Guidance for Industry and FDA Staff	

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: Luna1012X connected via wireless communication.

Operating System:	Windows 7/10, 32/64bit
CPU:	Intel Core i7 3.6G
Memory:	≥4 GB
Hard Disk:	640 GB
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 Luna1012X. 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 and IEC 60601-2-54 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 main modification from the predicate device is flexible Amorphous Silicon TFT Panel. Another main modification is structure design with different IP grade

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 (Mars1013X, K220668).

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 Luna1012X is substantially equivalent to predicate device with regards to safety and effectiveness.