October 9, 2025

iRay Imaging Technology (Haining) Limited
c/o Junjie Qian
No. 2, Caohejing RD.
Haining, Jiaxing, Zhejiang 314499
CHINA

Re: K252911
Trade/Device Name: Lux HD 2530 Detector (Lux HD 2530)
Regulation Number: 21 CFR 892.1680
Regulation Name: Stationary X-Ray System
Regulatory Class: Class II
Product Code: MQB
Dated: August 1, 2025
Received: September 12, 2025

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

Lu Jiang

Lu Jiang Ph.D.
Assistant Director
Diagnostic X-Ray Systems Team
DHT8B: Division of Radiologic Imaging
Devices 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: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K252911

Device Name
Lux HD 2530 detector (Lux HD 2530)

Indications for Use *(Describe)*

Lux HD 2530 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. Lux HD 2530 Detector 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.

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510 (k) SUMMARY OF SAFETY AND EFFECTIVENESS

(As Required by 21 CFR 807.92)

K252911

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

August 8, 2025

2. Submitter's Information [21 CFR 807.92(a)(1)]

Company Name:	iRay Imaging Technology (Haining) Limited
Company Address:	No. 2, Caohejing RD., Haining 314499, Jiaxing, Zhejiang, China
Contact Person:	Junjie Qian
Phone:	0573-87399739
Email:	Junjie.qian@iraygroup.com

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

Trade Name:	Lux HD 2530 Detector (Lux HD 2530)
Common Name:	Solid State X-Ray Imager
Model Name:	Lux HD 2530
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 Imaging Technology (Haining) Limited
Trade Name:	Lux HD 35 Detector (Lux HD 35)
	Lux HD 43 Detector (Lux HD 43)
Model Name:	Lux HD 35
	Lux HD 43
Product Code:	MQB
Classification Name:	Stationary X-Ray System
Regulation Number:	21 CFR 892.1680
Device Class:	Class II
FDA 510 (k) #:	K243556

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

Lux HD 2530 Detector is digital flat panel detector. They support the single frame mode, with the key component of TFT/PD image sensor flat panel of active area: 25cm × 30cm (Lux HD 2530 Detector). The differences between two models are overall change in the dimensions of the image receptor

The sensor plate of Lux HD 2530 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 Lux HD 2530 Detector is to convert the X-ray to digital image, with the application of high resolution X-ray imaging.

The Digital Radiographic Imaging Acquisition Software Platform - DR is part of the system, it is used to acquire, enhance, view image from Lux HD 2530 Detector. Based on the risks and intended use, documentation level of the software is basic

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

6.1. Indications for use

Lux HD 2530 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. Lux HD 2530 Detector is not intended for mammography or dental applications.

6.2. Suitable patient

Lux HD 2530 Detector 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.

6.3. Processing of input and output

When Lux HD 2530 Detector work 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: Lux HD 43 Detector Lux HD 35 Detector	Proposed Device: Lux HD 2530 Detector
510(K) Number	K243556	K252911
Intended Use	The Lux HD detectors are indicated for digital imaging solution designed for providing general radiographic system in all general-purpose diagnostic procedures.	Same
Indications for Use	Lux HD Detectors 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 devices are not intended for mammography or dental applications.	same
Classification Name	Stationary X-ray system	Same
Product Code	MQB	Same

Item	Predicate Device: Lux HD 43 Detector Lux HD 35 Detector	Proposed Device: Lux HD 2530 Detector
Regulation Number	21 CFR 892.1680	Same
Panel	Radiology	Same
Classification	II	Same
X-Ray Absorber (Scintillator)	CsI	Same
Installation Type	Wireless or Wired	Same
Readout Mechanism	Thin Film Transistor	Same
Image Matrix Size	Lux HD 35 Detector: 3500 ×4300pixels Lux HD 43 Detector: 4267 × 4267 pixels	2500 × 3000pixels
Pixel Size	100μm	Same
ADC Digitization	16 bit	Same
Effective Imaging Area	Lux HD 35 Detector: 350mm ×430mm Lux HD 43 Detector: 426.7 mm × 426.7mm	250mm × 300mm
Spatial Resolution	5.0 lp/mm	Same
Detective Quantum Efficiency (DQE)	0.54 at 1 lp/mm (RQA5, 2.5μGy)	Same

Item	Predicate Device: Lux HD 43 Detector Lux HD 35 Detector	Proposed Device: Lux HD 2530 Detector
Power Consumption	Max. 30W	Same
Communications	a) Wired: 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	Lux HD 35 Detector: 384mm×460mm×15mm Lux HD 43 Detector: 460mm×460mm×15mm	281.5mm×332.3mm×15 mm
Detector IP grade	IP67	Same
Power input port	10 pin port	Same
Frame material	Carbon fiber	Same
Surface pressure	Uniform load：300 kg over the whole area of the surface; Local load：100 kg on an area 4 cm diameter of center	Same
Operation	Temperature: +5 ~ +35℃ Humidity: 5 ~ 90% (Non-Condensing)	Same

Item	Predicate Device: Lux HD 43 Detector Lux HD 35 Detector	Proposed Device: Lux HD 2530 Detector
	Atmospheric pressure: 70 ~ 106 kPa Altitude: Max. 3000 meters	
Storage and Transportation: （detector）	Temperature: -10 to + 60ºC. (Excluding battery) Relative Humidity: 5 to 95%, non-condensing. Atmosphere: 700mBar ~1060mBar Altitude: Max. 3000 meter	Same
Software	Digital Radiographic Imaging Acquisition Software Platform – DR The software used for getting Digital X-ray radiography images from the flat panel detectors. The software is used to handle the DICOM protocol (DICOM 3.0). The software is responsible for the DR equipment management, acquisition and processing functions, to	Same

Item	Predicate Device: Lux HD 43 Detector Lux HD 35 Detector	Proposed Device: Lux HD 2530 Detector
	provide patient registration, scanning, image processing and other functions.	

8. **Minimum requirement for connection**

Lux HD 2530 Detector connected via wireless and wired communication.

Operating System:	Windows 11
CPU:	Intel Core i3- 8100 3.6GHz 4C 65W
Memory:	16GB (2x8GB) DDR4 2666 DIMM
Hard Disk:	1TB

9. X-ray exposure mode

The AED (Automatic Exposure Detection) trigger module is a unit can connect X-ray signal in the Lux HD 2530 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.

The DEC (Detector Exposure Control) trigger module is a unit can cutoff HVG output when patients need specified dose, which avoid extra dose absorbed by patients. Once the dose detected by the detector reaches the target value, the detector will send a cut-off signal to the high-voltage system. This signal indicates that no further exposure from HVG is required.

10. **Non-clinical study**

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 patients' skin have been evaluated with the FDA guidance "Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process". And the evaluation result assured the biological safety.

3) Non-clinical Considerations:

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 (Lux HD 35/43 detector, K243556).

4) Clinical Consideration:

Intended use, fundamental scientific technology, regulatory requirement, non-clinical performance, labeling, quality-assurance program keep the same with those of predicate device. Software keep the same with that of reference device except "image forwarding, image printing" function and literal name. There is no any negative change about clinical performance from predicate device.

5) Wireless testing

Wireless functionality and wireless coexistence testing in accordance with ANSI IEEE C63.27-2017 was performed. All test results are meet the standard requirements.

6) Cybersecurity testing

Cybersecurity threat modeling, risk assessment, and controls and testing were performed to comply with requirements specified in section 524B(b)(2) of the Federal Food, Drug, and Cosmetics Act to provide a reasonable assurance that the subject device with its wireless capabilities are cybersecure.

11. 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, applicant concludes that Lux HD 2530 Detector is substantially equivalent to predicate device with regards to safety and effectiveness.