



March 18, 2025

iRay Imaging Technology (Haining) Limited
% Junjie Qian
Registration & Regulatory Affairs Engineer
No. 2, Caohejing Rd.
Haining 314499
JIAXING, ZHEJIANG
CHINA

Re: K243556

Trade/Device Name: Lux HD 35 Detector (Lux HD 35); Lux HD 43 Detector (Lux HD 43)
Regulation Number: 21 CFR 892.1680
Regulation Name: Stationary X-Ray System
Regulatory Class: Class II
Product Code: MQB
Dated: August 20, 2024
Received: December 31, 2024

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,

Digitally signed by Gabriela M. Rodal -S for
Gabriela M. Rodal -S
S

Lu Jiang, Ph.D.
Assistant Director
Diagnostic X-Ray Systems Team
DHT8B: Division of Radiological Imaging Devices
and Electronic Products
OHT8: Office of Radiological Health
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

Indications for Use

Submission Number (if known)

K243556

Device Name

Lux HD 35 Detector (Lux HD 35);
Lux HD 43 Detector (Lux HD 43)

Indications for Use (Describe)

Lux HD 35 Detector and Lux HD 43 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. Lux HD 35 Detector and Lux HD 43 Detector are 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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iRay Imaging Technology (Haining) Limited [510(k)] Application

510 (k) SUMMARY OF SAFETY AND EFFECTIVENESS

(As Required by 21 CFR 807.92)

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

August 13, 2024

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 35 Detector (Lux HD 35)
Lux HD 43 Detector (Lux HD 43)
Common Name: Solid State X-Ray Imager
Model Name: Lux HD 35
Lux HD 43
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:

| | |
|------------------------------------|-------------------------|
| <u>Manufacturer:</u> | Carestream Health, Inc |
| <u>Trade Name:</u> | Focus HD 43 Detector |
| <u>Model Name:</u> | Focus HD 43 |
| <u>Product Code:</u> | MQB |
| <u>Classification Name:</u> | Stationary X-Ray System |
| <u>Regulation Number:</u> | 21 CFR 892.1680 |
| <u>Device Class:</u> | Class II |
| <u>FDA 510 (k) #:</u> | K213529 |

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

Lux HD 35 Detector and Lux HD 43 Detector are digital flat panel detector. They support the single frame mode, with the key component of TFT/PD image sensor flat panel of active area: 35cm×43cm (Lux HD 35 Detector)/42.67cm × 42.67cm (Lux HD 43 Detector) .The differences between two models are overall change in the dimensions of the image receptor

The sensor plate of Lux HD 35 Detector and Lux HD 43 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 35 Detector and Lux HD 43 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.

The Digital Radiographic Imaging Acquisition Software Platform - DR is part of the system, it is used to acquire, enhance, view image from Lux HD 35 Detector and Lux HD 43 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 35 Detector and Lux HD 43 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. Lux HD 35 Detector and Lux HD 43 Detector are not intended for mammography or dental applications.

6.2. Suitable patient

Lux HD 35 Detector and Lux HD 43 Detector 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 Lux HD 35 Detector and Lux HD 43 Detector work continuously, it can automatically distinguish X-ray and output an imaging for diagnosis of disease, injury, or of any applicable health problem.

iRay Imaging Technology (Haining) Limited [510(k)] Application

7. Technological Characteristic [21 CFR 807.92(a)(6)]

| Item | Predicate Device: Focus HD 43 Detector | Proposed Device: Lux HD 35 Detector Lux HD 43 Detector | Reference device Mars1417V-PSI |
|---------------------|--|---|---|
| 510(K) Number | K213529 | K243556 | K161730 |
| Intended Use | The Focus HD 43 Detector is indicated for digital imaging solution designed for providing general radiographic system in all general-purpose diagnostic procedures. | Same | Same |
| Indications for Use | Focus HD 43 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. | Lux HD 35 Detector and Lux HD 43 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 devices are not intended for mammography or dental applications. | Mars1417V-PSI 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. |

iRay Imaging Technology (Haining) Limited [510(k)] Application

| Item | Predicate Device: Focus HD 43 Detector | Proposed Device: Lux HD 35 Detector Lux HD 43 Detector | Reference device Mars1417V-PSI |
|-------------------------------|---|---|-----------------------------------|
| Classification Name | Stationary X-ray system | Same | Same |
| Product Code | MQB | Same | Same |
| Regulation Number | 21 CFR 892.1680 | Same | Same |
| Panel | Radiology | Same | Same |
| Classification | II | Same | Same |
| X-Ray Absorber (Scintillator) | CsI | CSI | Gd ₂ O ₂ S |
| Installation Type | Wireless, Portable | Wireless or Wired | Wireless, Portable |
| Readout Mechanism | Thin Film Transistor | Same | Same |
| Image Matrix Size | 4267 × 4267 pixels | Lux HD 35 Detector: 3500 × 4300pixels Lux HD 43 Detector: 4267 × 4267 pixels | 2304 × 2800 pixels |
| Pixel Size | 100µm | 100µm | 150µm |
| ADC Digitization | 16 bit | 16 bit | 14 bit |
| Effective Imaging Area | 426.7 mm × 426.7mm | Lux HD 35 Detector: 350mm × 430mm Lux HD 43 Detector: 426.7 mm × 426.7mm | 355 mm × 434mm |

iRay Imaging Technology (Haining) Limited [510(k)] Application

| Item | Predicate Device: Focus HD 43 Detector | Proposed Device: Lux HD 35 Detector Lux HD 43 Detector | Reference device Mars1417V-PSI |
|------------------------------------|---|---|--|
| Spatial Resolution | 5.0 lp/mm | 5.0 lp/mm | 3.4 lp/mm |
| Detective Quantum Efficiency (DQE) | 0.54 at 1 lp/mm (RQA5, 2.5μGy) | 0.54 at 1 lp/mm (RQA5, 2.5μGy) | 0.27 at 0.5 lp/mm (RQA5, 3.2μGy) |
| Power Consumption | Max. 42W | Lux HD 35 Detector: Max. 30W Lux HD 43 Detector: Max. 30W | Max. 13W |
| Communications | a) Wired (only for service) : Gigabit Ethernet (1000BASE-T) b) Wireless: IEEE 802.11a/b/g/n/ac (2.4 GHz / 5 GHz) | a) Wired: Gigabit Ethernet (1000BASE-T) b) Wireless: IEEE 802.11a/b/g/n/ac (2.4 GHz / 5 GHz) | a) Wired: Gigabit Ethernet (1000BASE-T) b) Wireless: IEEE 802.11a/b/g/n (2.4 GHz / 5 GHz) |
| Imaging protect Plate | Carbon Fiber Plate | Same | Same |
| Cooling | Air cooling | Same | Same |
| Dimensions | 460 mm × 460 mm × 15mm | Lux HD 35 Detector 384mm× 460 mm × 15mm Lux HD 43 Detector 460mm× 460 mm × 15mm | 384 mm × 460 mm × 15mm |
| Detector IP grade | IP56 | IP67 | / |

iRay Imaging Technology (Haining) Limited [510(k)] Application

| Item | Predicate Device: Focus HD 43 Detector | Proposed Device: Lux HD 35 Detector Lux HD 43 Detector | Reference device Mars1417V-PSI |
|---|---|--|--|
| Power input port | 10 pin port | 10 pin port | 4 Pin port |
| Frame material | Aluminum alloy | Carbon fiber | Aluminum alloy |
| 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 | 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: +5 ~ +35°C Humidity: 5 ~ 90% (Non-Condensing) Atmospheric pressure: 70 ~ 106 kPa Altitude: Max. 3000 meters | Temperature: +5 ~ +35°C Humidity: 5 ~ 90% (Non-Condensing) Atmospheric pressure: 70 ~ 106 kPa Altitude: Max. 3000 meters | Temperature: +5 ~ +35°C Humidity: 30 ~ 75% (Non-Condensing) Atmospheric pressure: 70 ~ 106 kPa Altitude: Max. 3000 meters |
| Storage and Transportation: (detector) | Temperature: -20 ~ +55°C Humidity: 5 ~ 95% (Non-Condensing) Atmospheric pressure: 70 ~ 106 kPa Altitude: Max. 3000 meters | Temperature: -10 to + 60°C. (Excluding battery) Relative Humidity: 5 to 95%, non-condensing. Atmosphere: 700mBar ~1060mBar Altitude: Max. 3000 meter | Temperature: -20 ~ +55°C Humidity: 10 ~ 90% (Non-Condensing) Atmospheric pressure: 70 ~ 106 kPa Altitude: Max. 3000 meters |

iRay Imaging Technology (Haining) Limited [510(k)] Application

| Item | Predicate Device: Focus HD 43 Detector | Proposed Device: Lux HD 35 Detector Lux HD 43 Detector | Reference device Mars1417V-PSI |
|----------|---|--|---|
| Software | <p>SDK(include iDetector)</p> <p>The software 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 beside DR system manufacturers.</p> | <p>Digital Radiographic Imaging Acquisition Software Platform – DR</p> <p>The software used for getting Digital X-ray radiography images from the flat panel detectors.</p> <p>The software is used to handle the DICOM protocol (DICOM 3.0).</p> <p>The software is responsible for the DR equipment management, acquisition and processing functions, to provide patient registration, scanning, image processing and other functions.</p> | <p>iRayDR</p> <p>The software used for getting Digital X-ray radiography images from the flat panel detectors.</p> <p>The software is used to handle the DICOM protocol (DICOM 3.0).</p> <p>The software is responsible for the DR equipment management, acquisition and processing functions, to provide patient registration, scanning, image processing, image forwarding, image printing and other functions.</p> |

iRay Imaging Technology (Haining) Limited [510(k)] Application

| Item | Predicate Device: Focus HD 43 Detector | Proposed Device: Lux HD 35 Detector Lux HD 43 Detector | Reference device Mars1417V-PSI |
|---------------------------------|---|---|-----------------------------------|
| Utilized FDA guidance documents | <ol style="list-style-type: none"> 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”. 7. Design Control Guidance For Medical Device Manufacturers | <p>Same</p> <p>Additionally, the following FDA guidance documents are applied</p> <ol style="list-style-type: none"> 1. Content of Premarket Submissions for Device Software Functions Guidance for Industry and Food and Drug Administration Staff June 2023 2. Pediatric Information for X-ray Imaging Device Premarket Notifications Guidance for Industry and Food and Drug Administration Staff November 2017 3. Cybersecurity in Medical Devices: Quality System Considerations and Content of Premarket | / |

iRay Imaging Technology (Haining) Limited [510(k)] Application

| Item | Predicate Device: Focus HD 43 Detector | Proposed Device: Lux HD 35 Detector Lux HD 43 Detector | Reference device Mars1417V-PSI |
|------|--|--|-----------------------------------|
| | 8. Appropriate Use of Voluntary Consensus Standards in Premarket Submissions for Medical Devices. 9. The Special 510(k) Program | Submissions Guidance for Industry and Food and Drug Administration Staff September 2023 | |

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) Minimum configuration: Lux HD 43 Detector and Lux HD 35 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

3) X-ray exposure mode

The AED trigger module is a unit can connect X-ray signal in the Lux HD 35 Detector and Lux HD 43 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. **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 (Focus HD 43 detector, K213529).

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.

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, applicant concludes that Lux HD 35 Detector and Lux HD 43 Detector are substantially equivalent to predicate device with regards to safety and effectiveness.