February 3, 2023

iRay Imaging Technology (Haining) Limited
%Mr. Jeffrey Wu
Registration & Regulation Affairs Engineer
No. 2, Caohejing RD., Haining 314499, Jiaxing
Haining, Zhejiang 314499
CHINA

Re: K230059
Trade/Device Name: Digital Flat Panel Detector
Regulation Number: 21 CFR 892.1680
Regulation Name: Stationary x-ray system
Regulatory Class: Class II
Product Code: MQB
Dated: December 29, 2022
Received: January 9, 2023

Dear Mr. Wu:

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,

Lu Jiang
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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

SECTION 4

Indications for use FDA-3881

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)*
K230059

Device Name
Digital Flat Panel Detector

Indications for Use *(Describe)*
Venu1748V and DRX-LC, as a major imaging component, are supplied to the manufacturers of medical diagnostic X-ray photography systems, and used in conjunction with the medical diagnostic X-ray photography system to image the object to be checked. They are capable of outputting the acquired static images to a processing device after acquisition.

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.

SECTION 6

510 (k) SUMMARY OF SAFETY AND EFFECTIVENESS

510 (k) SUMMARY OF SAFETY AND EFFECTIVENESS

(As Required by 21 CFR 807.92)
K230059

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

December 15, 2022

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, P.R.China
Contact Person:	Jeffrey Wu
Phone:	86-21-50720539
Fax:	86-21-50720561
Email:	guo.wu@iraygroup.com

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

Trade Name:	Digital Flat Panel Detector
Common Name:	Solid State X-Ray Imager
Model Name:	Venu1748V DRX-LC
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:	Digital Flat Panel Detector
Model Name:	Venu1748V

Product Code:	MQB
Classification Name:	Stationary x-ray system
FDA 510 (k) #:	K220536

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

Venu1748V and DRX-LC digital flat panel detector (Hereinafter referred to as Venu1748V and DRX-LC) are digital large-sized X-ray flat panel detector (FPD) with wireless function based on amorphous silicon (a-Si) thin film transistor (TFT) technology.

Two models Venu1748V and DRX-LC are totally same except for the model name, trade mark, artwork of the protection film. They using cesium iodide (CsI) scintillator, and employ a 3064×8696 active pixel matrix with a pixel size of 139 μm, providing high-quality radiographic images.

Supporting high-speed wireless communication, the equipment can be powered by internal rechargeable battery packs or/and external power charger, making it more flexible and easy to integrate and operate.

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.

iDetector is a tool software based on iRay FPD(Flat Panel Detector) and SDK(Software Development Kit). It can be used for detector configuration, image acquisition, and calibration. So that users can evaluate the performance of iRay detectors at the first time. Also, iDetector can be used as a demonstration program to learn the process controlling and functionality of iRay Detectors and do assessment at user application developing time. This software is moderate level of concern. iDetector does not support image processing after collection.

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

6.1. Indications for use

Venu1748V and DRX-LC, as a major imaging component, are supplied to the manufacturers of medical diagnostic X-ray photography systems, and used in

conjunction with the medical diagnostic X-ray photography system to image the object to be checked. They are capable of outputting the acquired static images to a processing device after acquisition.

6.2. Suitable patient

Two models provide digital X-ray imaging technology for the diagnosis of disease, injury, or any health problem, suitable for all common anatomical large objects that require X-ray examination including long bones or the spine.
They are not suitable for mammography, dental photography, and dynamic imaging photography. Do not use it in pregnant women.

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: Digital Flat Panel Detector	Proposed Device: Digital Flat Panel Detector
Model Name:	Venu1748V	Venu1748V, DRX-LC
Configuration Name:	Venu1748V	Venu1748V-WF, DRX-LC
510(K) Number:	K220536	K230059
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:	Fixed	Transportable
Degree of protection against electrical shock:	No such Part	Type B

Item	Predicate Device: Digital Flat Panel Detector	Proposed Device: Digital Flat Panel Detector
Power supply:	AC power	AC power and battery
Detector structure:	Amorphous silicon TFT	Same
Dimensions:	1271.4mm×586.6mm×20.8mm	Same
Image Matrix Size:	3064 × 8696 pixels	Same
Pixel Pitch:	139μm	Same
Effective Imaging Area:	425.8mm × 1208.7mm	Same
ADC Digitization:	16 bit	Same
Spatial Resolution:	Min. 3.6lp/mm	Same
Modulation Transfer Function (MTF):	56% at 1.0 lp/mm	58% at 1.0 lp/mm
Detective Quantum Efficiency (DQE):	24% at 1.0 lp/mm	38% at 1.0 lp/mm
Accessory:	Medical adapter, Control Box	Medical adapter, Control Box, Wireless USB adapter, Battery, Detector Cart, Detector weight bearing cap, Battery-Charger
Imaging protect Plate:	Carbon Fiber Plate	Same
Power Consumption:	Max. 50W	Same
Communications:	Wired	Wired and wireless
Cooling:	Air cooling	Same
Protection against matter/Water	IPX0	Same
Operation:	Temperature: 5 to 35℃ Humidity: 10 to 90% (Non-Condensing) Atmospheric pressure: 70 to 106 kPa Altitude: Max. 3000 meters	Temperature: 5 to 35℃ Humidity: 10 to 90% (Non-Condensing) Atmospheric pressure: 70 to 106 kPa Altitude: Max. 3000 meters
Storage and Transportation:	Temperature: -20 °C ~ 55 °C Humidity: 5% ~ 95% (Non-Condensing)	Temperature: -20 °C ~ 55 °C Humidity: 5% ~ 95% (Non-Condensing)

Item	Predicate Device: Digital Flat Panel Detector	Proposed Device: Digital Flat Panel Detector
（detector）	Atmospheric pressure: 70kPa~106kPa Altitude: Max. 3000 meters	Atmospheric pressure: 70kPa~106kPa Altitude: Max. 3000 meters
Software	iDetector(edition: 4.1.0.8905)	iDetector(edition: 4.1.3.10016)

8. **System requirements to operate with other radiographic system components**

1) Recommended Generator Specification:

Energy range: 40~150kV

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: Venu1748V and DRX-LC connected via wired communication or wireless.

Operating System:	Windows 7 64bit, or even higher
CPU:	Intel Core i5 3.6G, or even higher
Memory:	8G DDR3 or higher
Hard Disk:	640 G or higher
Netwoek Card:	Intel Pro EXP9301CT PRO or higher

3) X-ray exposure mode

The inner trigger module is a unit can connect X-ray signal in the Venu1748V and DRX-LC. 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. Nonclinical study

1) Electrical Safety and EMC testing:

   Electrical, mechanical, environmental safety and performance testing according to IEC/ES 60601-1 and IEC60601-2-54 were 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 top cover surface film of the detector may contact patients' skin, this has been evaluated with the ISO 10993-1.

3) Nonclinical Considerations:

   According to the *Guidance for the Submission of 510(k)s for Solid State X-ray Imaging Devices*, the non-clinical studies have been performed and the results have shown that the Venu1748V and DRX-LC are substantially equivalent to the predicate devices on the Market (K220536):

   Dose to output signal transfer function, Signal to noise ratio, uniformity, Defect, Minimum triggering dose rate, Modulation transfer function (MTF), Spatial resolution, Low contrast resolution and Image Acquisition time.

   According to the *Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices*, the software SDK(contains iDetector) classifies the hazards, defines requirements specification and design specification, all the specification pass all the test cases and complies the intended design specification.

4) Clinical Consideration:

   Clinical data is not needed to characterize performance and establish substantial equivalence. The non-clinical test data characterizes all performance aspects of the device based on well-established scientific and engineering principles.

5) Cybersecurity:

According to the *Guidance for Content of Premarket Submissions for Management of Cybersecurity in Medical Devices*, the Venu1748V and DRX-LC had passed the assessment related to Cybersecurity.

10. Conclusion

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 Imaging Technology (Haining) Limited Concludes that iRay Venu1748V and DRX-LC are substantially equivalent to predicate device with regards to safety and effectiveness.