June 29, 2022

iRay Technology Taicang Ltd.
℅ Guo Wu
Registration & Regulation Affairs Engineer
No. 33 Xinggang Rd. Taicang Port Economic & Technological
Development Zone
Taicang, Jiangsu 215434
CHINA

Re: K221714
Trade/Device Name: Flat Panel Detector
Regulation Number: 21 CFR 892.1680
Regulation Name: Stationary X-Ray System
Regulatory Class: Class II
Product Code: MQB
Dated: May 10, 2022
Received: June 13, 2022

Dear Guo 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,

Laurel Burk, 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

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)*
K221714

Device Name
Flat Panel Detector

Indications for Use *(Describe)*
Venu1717X 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 general–purpose diagnostic procedures.

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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K221714

510 (k) SUMMARY OF SAFETY AND EFFECTIVENESS

(As Required by 21 CFR 807.92)

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

April 15, 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: Guo Wu

Phone: 0512- 50720539

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Email: guo.wu@iraygroup.com

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

Trade Name: Flat Panel Detector

Common Name: Solid State X-Ray Imager

Model Name: Venu1717X

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: Mars1717V-VSI

Product Code: MQB

Classification Name: Stationary x-ray system

FDA 510 (k) #: K201043

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

Venu1717X is a cassette-size tethered X-ray flat panel detector based on amorphous silicon thin-film transistor technology. It is designed to provide the high quality radiographic image which contains an active matrix of 3070×3070 with 139um pixel pitch. The scintillator of Venu1717X is CsI(Caesium Iodide). The technology of CsI direct growth reduces the exposure dose and improves the image quality. Since Venu1717X supports multiple trigger modes, it can satisfy both of the general DR system and retrofit DR system.

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. The iRay SDK is unchanged from the predicate device.

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

6.1. Intended Use

Venu1717X is indicated for digital imaging solutions designed to provide general radiographic diagnosis for human anatomy including adults only. It is intended to replace film/screen systems in all general–purpose diagnostic procedures.
This equipment provides digital X-ray imaging for diagnosis of disease, injury, or any applicable health problem. The image is obtained as the result of X-ray passing through the human body and detected by the equipment.
iRay will provide equipment and software support for integration of system.

6.2. Suitable patient

This panel is not intended for mammography or dental applications, and not recommend for pregnant women and new born.

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: Wireless Digital Flat Panel Detector	Proposed Device: Flat Panel Detector
510(K) Number	K201043	K221714
Intended Use	The Mars1717V-VSI Wireless Digital Flat Panel Detector is indicated for digital imaging solution designed for providing general radiographic system in allgeneral-purpose diagnostic procedures.	This equipment provides digital X-ray imaging for diagnosis of disease, injury, or any applicable health problem. The image is obtained as the result of X-ray passing through the human body and detected by the equipment. iRay will provide equipment and software support for integration of system.
Indications for Use	Mars1717V-VSI 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.	Venu1717X is indicated for digital imaging solutions designed to provide general radiographic diagnosis for human anatomy including adults only. It is intended to replace film/screen systems in all general–purpose diagnostic procedures.
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	Wired, Portable
Detector structure:	Amorphous silicon TFT	Same

Item	Predicate Device: Wireless Digital Flat Panel Detector	Proposed Device: Flat Panel Detector
Dimensions:	460 mm× 460 mm × 15 mm	Same
Image Matrix Size:	3072 × 3072 pixels	Same
Pixel Pitch:	139μm	Same
Effective Imaging Area:	427mm×427mm	Same
ADC Digitization	16 bit	Same
Spatial Resolution	Min. 3.6lp/mm	Min. 3.4 lp/mm
Modulation Transfer Function (MTF)	0.65 at 1 lp/mm	0.66 at 1 lp/mm
Detective Quantum Efficiency (DQE)	0.40 at 1 lp/mm (RQA5, 2.5μGy)	0.28 at 1 lp/mm (RQA5, 2.5μGy)
Imaging protect Plate:	Carbon Fiber Plate	Same
Power Consumption:	Max. 30W	Max. 20W
Communications:	a) Wired（only for service）: Gigabit Ethernet (1000BASE-T) b) Wireless: IEEE 802.11a/b/g/n/ac (2.4 GHz / 5 GHz)	Wired: Gigabit Ethernet (1000BASE-T)
Cooling:	Air cooling	Same
Protection against matter/Water	IPX1	IPX1
Protection against shock	Type B applied part	Same
Operation:	Temperature: +5 ~ +35℃ Humidity: 5 ~ 95% (Non-Condensing) Atmospheric pressure: 55 ~ 106 kPa Altitude: Max. 3000 meters	Temperature: +5 ~ +35℃ Humidity: 30 ~ 80% (Non-Condensing) Atmospheric pressure: 70 ~ 106 kPa Altitude: Max. 3000 meters
Storage and Transportation: （detector）	Temperature: -10 ~ +55℃ Humidity: 5 ~ 95% (Non-Condensing)	Temperature: 10 to 55℃ Humidity: 10 ~ 90% (Non-Condensing)

Item	Predicate Device: Wireless Digital Flat Panel Detector	Proposed Device: Flat Panel Detector
	Atmospheric pressure: 55 ~ 106 kPa Altitude: Max. 3000 meters	Atmospheric pressure: 70 ~ 106 kPa Altitude: Max. 3000 meters
Software	iDetector	iDetector

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: Venu1717X connected via wired communication.

Operating System:	Windows 10 or above 32/64bit
CPU:	Intel Core i7 dual core, or even higher
Memory:	4G or higher
Hard Disk:	160 G or higher
LAN Card:	Intel Gigabit CT adapter Network Interface Card or equivalent

3) X-ray exposure mode

The inner trigger module is a unit can connect X-ray signal in the Venu1717X. 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 and painting materials of the detector may contact patients' skin, this has been evaluated with the ISO 10993-1. And the evaluation results and test result assured the safety the same as the predicate device.

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 Venu1717X is substantially equivalent to the predicate devices on the Market (K201043):

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:

A concurrence study of 30 clinical images was conducted to compare the performance of theVenu1717X to that of the predicate device (Mars1717V-VSI, K201043).

Clinical images were provided; these images were not necessary to establish substantial equivalence based on the differences from the predicate but they provide further evidence in addition to the laboratory performance data to show that the complete system works as intended.

There was no significant difference between the images of the Venu1717X and those of the predicate device.

5) Cybersecurity:

According to the *Guidance for Content of Premarket Submissions for Management of Cybersecurity in Medical Devices*, the Venu1717X 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 Technology Taicang Ltd. Concludes that iRay Venu1717X is substantially equivalent to predicate device with regards to safety and effectiveness.