April 28, 2022

iRay Technology Taicang Ltd.
℅ Jeffrey Wu
Regulatory Affairs Engineer
No. 33 Xinggang Road, Taicang Port Economic and
Technological Development Zone
Taicang, Jiangsu 215434
CHINA

Re: K220536
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: February 21, 2022
Received: February 24, 2022

Dear Jeffrey 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
Division of Radiological Health
OHT7: Office of In Vitro Diagnostics
and 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)*

K220536

Device Name
Digital flat panel detector

Indications for Use *(Describe)*

The Venu1748V flat panel detector is provided as an imaging component to the system manufacturer. It is mainly used in long bones, spine and other inspection fields. After collecting static images, the imaged data is output to the processing equipment.

This device is suitable for providing radiography imaging for adult via DR system. The remaining notes depend on the final DR system.

It is not intended for mammography, dental applications, neonatal and fluoroscopy.

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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510 (k) SUMMARY OF SAFETY AND EFFECTIVENESS

(As Required by 21 CFR 807.92)

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

February 21, 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

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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 (Flat Panel/Digital Imager)

Model Name: Venu1748V

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: Vieworks Co., Ltd.

Trade Name: VIVIX-S 1751S

Model Name: VIVSX-S 1751S

Product Code: MQB

Classification Name:	Stationary X-Ray System
Regulation Number:	21 CFR 892.1680
Device Class:	Class II
FDA 510 (k) #:	K190611

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

Digital flat panel detector is a cassette-size wired X-ray flat panel detector based on amorphous silicon thin-film transistor technologies. It was developed to provide X - Ray image, which contains an active matrix of 3064×8696 with 139um pixel pitch. Detector's scintillator is CsI(Cesium iodide). The biggest feature of Venu1748V is that it supports imaging of large-scale objects, including long bones and complete spine detection.

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

6.1. Indications for use

The Venu1748V flat panel detector is provided as an imaging component to the system manufacturer. It is mainly used in long bones, spine and other inspection fields. After collecting static images, the imaged data is output to the processing equipment.

This device is suitable for providing radiography imaging for adult via DR system. The remaining notes depend on the final DR system.

It is not intended for mammography, dental applications, neonatal and fluoroscopy.

6.2. Suitable patient

This device is not intended for mammography and applications.

This device is suitable for providing radiography imaging for adult via DR system. The remaining notes depend on the DR system.

In addition, it is also prohibited for use on pregnant women. Shielding of none-inspection body areas is necessary during X-ray exposure.

6.3. Processing of input and output

The sensor plate 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.

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

Item	Predicate Device: VIVIX-S 1751S	Proposed Device: Digital flat panel detector Venu1748V
Model name	VIVIX-S 1751S	Venu1748V
510(K) Number	K190611	To be assigned
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):	Gd_2O_2S:Tb (Gadolinium oxysulfide)	CsI
Installation Type:	Portable	Same
Detector structure:	Amorphous silicon TFT	Same
Dimensions:	1357.0mm×532.0mm×30.0mm	1271.4mm×586.6mm×20.8mm
Max. Image Matrix Size:	3072 × 9216 pixels	3064 × 8696 pixels
Pixel Pitch:	140μm	139μm
Max. Effective Imaging Area(H×V):	430.08mm × 1290.24mm	425.8mm × 1208.7mm
Spatial resolution	3.5 lp/mm	3.4 lp/mm
Greyscales	16 bit	Same
Modulation Transfer Function (MTF)	40% at 1.0 lp/mm	56% at 1.0 lp/mm

Item	Predicate Device: VIVIX-S 1751S	Proposed Device: Digital flat panel detector Venu1748V
Detective Quantum Efficiency (DQE)	20% at 1.0 lp/mm	24% at 1.0 lp/mm
Power Consumption:	Max. 72 W	Max. 50 W
Communications:	Wired LAN	Same
Cooling:	Air cooling	Same
Protection against matter/Water	IPX0	Same
Operation:	Temperature: 10 to 35℃ Humidity: 30 to 85% (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: （detector）	Temperature: -15 to 55℃ Humidity: 10 to 90% (Non-Condensing) Atmospheric pressure: 50 ~ 106 kPa Altitude: Max. 3000 meters	Temperature: -20 °C ~ 55 °C Humidity: 5% ~ 95% (Non-Condensing) Atmospheric pressure: 70kPa~106kPa Altitude: Max. 3000 meters
Software	VXvue	iDetector

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

8.1. 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 Venu1748V is compatible with the X-ray generators with the specifications described above.

8.2. Application Program Interface (API) for system integration manufacturer

Peripheral hardware: the Venu1748V connected via wired LAN cable communication.

Operating System:	Windows 7 64bit
CPU:	Intel Core i5 3.6GHz
Memory:	8G DRR3
Hard Disk:	640 GB
Network Board:	Inter Pro EXP9301CT PRO

8.3. X-ray exposure mode

The inner trigger module is a unit can connect X-ray signal in the Venu1748V. 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

9.1. 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.

9.2. 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 is substantially equivalent to the predicate devices on the Market (K190611):

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 iDtector classifies the hazards, defines requirements specification and design specification, all the specification pass all the test cases and complies the intended design specification.

9.3. 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.

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 Venu1748V is substantially equivalent to predicate device with regards to safety and effectiveness.