October 20, 2022

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

Re: K222886
Trade/Device Name: Mercu1717V
Regulation Number: 21 CFR 892.1680
Regulation Name: Stationary x-ray system
Regulatory Class: Class II
Product Code: MQB
Dated: September 13, 2022
Received: September 23, 2022

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 (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)*
K222886

Device Name
Mercu1717V

Indications for Use *(Describe)*
Mercu1717V Digital Flat Panel 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.

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)

K222886

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

July 13, 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:	Junjie. Qian
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Email:	junjie.qian@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:	Mercu1717V
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:	Flat Panel Detectors
Model Name:	Venu1717X
Product Code:	MQB
Classification Name:	Stationary X-Ray System
Regulation Number:	21 CFR 892.1680
Device Class:	Class II
FDA 510 (k) #:	K221714

5. Identification of Reference Devices(s) [21 CFR 807.92(a)(3)]

Manufacturer:	CareRay Digital Medical Technology Co., Ltd.
Trade Name:	X-ray Flat Panel Detectors
Model Name:	CareView 3600RF
Product Code:	MQB
Classification Name:	Stationary X-Ray System
Regulation Number:	21 CFR 892.1680
Device Class:	Class II
FDA 510 (k) #:	K202995

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

Mercu1717V Digital Flat Panel Detectors (Hereinafter referred to as Mercu1717V) supports dynamic imaging and static imaging.

The sensor plate of Mercu1717V 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 cable.

The major function of the Mercu1717V is to convert the X-ray to digital image, with the application of high-resolution X-ray imaging. Mercu1717V can get single image and it also can get dynamic image. Both kinds of detectors are the key component of DR system, enable to complete the digitalization of the medical X-ray imaging with the DR system software.

The iRay DR used for digital X-ray radiography image from the digital flat panel detectors. iRay DR is used to handle the DICOM protocol (DICOM 3.0). iRay DR has many functions such as image acquisition, image enhancement processing and editing image or information.

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

7.1. Indications for use

Mercu1717V digital flat panel 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.

6.2. Suitable patient

It 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. The remaining notes depend on the DR system.

6.3. Processing of input and output

Mercu1717V Digital flat panel detector get signal from high-voltage generator, and then it gets ready to output radiographic imaging for diagnosis of disease, injury, or of any applicable health problem to iRayDR installed in PC.

iRayDR get raw image and output clinical image after enhancement processing for raw image is finished.

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

Item	Predicate Device: Venu1717X Digital Flat Panel Detector	Reference Device: CareView 3600RF X-ray Flat Panel Detector	Proposed Device: Mercu1717V Digital Flat Panel Detector
510(K) Number	K221714	K202995	K222886
Intended Use	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.	The CareView 3600RF 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 product is not intended for mammography applications.	Mercu1717V Digital Flat Panel Detector is indicated for digital imaging solution designed for providing general radiographic system in all general-purpose diagnostic procedures.
Indications for 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	/	Mercu1717V 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

Item	Predicate Device: Venu1717X Digital Flat Panel Detector	Reference Device: CareView 3600RF X-ray Flat Panel Detector	Proposed Device: Mercu1717V Digital Flat Panel Detector
	all general–purpose diagnostic procedures.		mammography or dental applications.
Classification Name	Stationary X-ray system	Stationary X-ray system	Same
Product Code	MQB	MQB	Same
Regulation Number	21 CFR 892.1680	21 CFR 892.1680	Same
Panel:	Radiology	Radiology	Same
Classification:	II	II	Same
X-Ray Absorber (Scintillator):	CSI	GOS	CSI
Installation Type:	Wired	Same	Same
Readout Mechanism:	Thin Film Transistor	Same	Same
Image Matrix Size:	3072 × 3072 pixels	5632 × 2816 pixels	Min. 1024 × 1024 pixels (@binning 3×3) Max.3072 ×3072 pixels (@binning 1×1)
Pixel Size:	139μm	154 μm	139μm
ADC Digitization	16 bit	Same	Same
Effective Imaging Area:	427mm×427mm	867.5mm × 433.1 mm	Min.285mm×285mm (@zoom on) Max.427mm × 427mm (@zoom off)
Spatial Resolution:	Min. 3.4 lp/mm	Same	Same

Item	Predicate Device: Venu1717X Digital Flat Panel Detector	Reference Device: CareView 3600RF X-ray Flat Panel Detector	Proposed Device: Mercu1717V Digital Flat Panel Detector
MTF	0.66 at 1 lp/mm	0.75 at 0.5lp/mm 0.5 at 1lp/mm	0.78 at 0.5lp/mm 0.55 at 1lp/mm
Detective Quantum Efficiency (DQE)	0.28 at 1 lp/mm (RQA5, 2.5μGy)	0.28 at 0.5 lp/mm 0.20 at 1 lp/mm (RQA5, 3.2μGy)	0.4 at 0.5 lp/mm 0.35 at 1 lp/mm (RQA5, 2.5μGy)
Power Consumption:	Max. 20W	~50W	18 W
Communications:	Gigabit Ethernet	Same	Same
Imaging protect Plate:	Carbon Fiber Plate	Same	Same
Cooling:	Air cooling	Same	Same
Protection against matter/water	IPX1	/	IPX1
Dimensions:	460 mm× 460 mm × 15 mm	916.9 mm × 486.4 mm × 42.8 mm	460 mm × 460 mm × 15mm
Frame rate	/	3.5fps@1×1 15fps@2×2 25fps@4×4	5fps@1×1 20fps@2×2 30fps@3×3
Operation:	Temperature: +5 ~ +35℃ Humidity: 30 ~ 80% (Non-Condensing) Atmospheric pressure: 70 ~ 106	Temperature: +10 ~ +40℃ Humidity: 30 ~ 75% (Non-Condensing) Atmospheric pressure: 700 ~ 1060 hPa	Temperature: +10 ~ +35℃ Humidity: 20 ~ 90% (Non-Condensing) Atmospheric pressure: 700 ~ 1060 mbar Altitude: Max. 3000 meters

Item	Predicate Device: Venu1717X Digital Flat Panel Detector	Reference Device: CareView 3600RF X-ray Flat Panel Detector	Proposed Device: Mercu1717V Digital Flat Panel Detector
	kPa Altitude: Max. 3000 meters	Altitude: Max. 3000 meters	
Storage and Transportation:（detector）	Temperature: 10 ~ 55℃ Humidity: 10 ~ 90% (Non-Condensing) Atmospheric pressure: 70 ~ 106 kPa Altitude: Max. 3000 meters	Temperature: -20 ~ +55℃ Humidity: 10 ~ 90% (Non-Condensing) Atmospheric pressure: 700 ~ 1060 hPa Altitude: Max. 3000 meters	Temperature: -10 ~ +55℃ Humidity: 10 ~ 95% (Non-Condensing) Atmospheric pressure: 700 ~ 1060 mbar Altitude: Max. 3000 meters
Software	iDetector	CareRay software provides a set of predefined APIs（Application Programming Interfaces）, an adapter layer between a CareView 3600RF detector and an upstream program on the client side, commonly known as DROC（Digital Radiography Operator Console）. DROC communicates with the CareRay	The Mercu1717V Digital Flat Panel Detector is supported by software, named iRayDR. The iRayDR used for getting digital X-ray radiography images from the digital flat panel detectors. iRay DR is used to handle the DICOM protocol (DICOM 3.0). iRay DR has many functions such as patient registration, image acquisition, image display, image processing and image archiving.

Item	Predicate Device: Venu1717X Digital Flat Panel Detector	Reference Device: CareView 3600RF X-ray Flat Panel Detector	Proposed Device: Mercu1717V Digital Flat Panel Detector
		detectors via APIs. In general, APIs are provided in the form of DLL （Dynamic-Link Libraries） files. The upstream program imports these DLL files and calls relevant API commands to manipulate a CareView 3600RF detector-query status, select application mode, calibrate detector, acquire images, and preprocess images-without caring about the implementation details of the algorithm or workflow under the hood.	Image processing refers to some post-processing tools for the acquired image, including three parts of the common tools, the image post-processing tools and the measurement tools. Common tools: zoom, rotate, etc. Post-processing tools: adjust image contrast, brightness, etc. Measurement tools: line measurement, angle measurement. iRayDR software is of Moderate level of concern.

9. **<u>System requirements to operate with other radiographic system components</u>**

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 iRay's service office.

2) Peripheral hardware: Mercu1717V connected via wired communication.

Operating System:	Windows 10, 64bit
CPU:	Intel Core i5 8400 2.8G
Memory:	16G DDR4
Hard Disk:	1T SSD
LAN Card:	Intel Pro EXP9301CT PRO Gigabit Network Adapter with PCIe interface

3) X-ray exposure mode

The digital flat panel detector gets ready to output image after it receive signal form high-voltage generator. The digital flat panel detector stops outputting image when there is no signal from high-voltage generator

10. <u>Substantial Equivalence [21 CFR 807.92(b)(1) and 807.92(b)(2)]</u>

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 digital flat panel detector is not intended to be touched by patient, so evaluation of bio-compatibility is not necessary.

3) Non-clinical Considerations:

The non-clinical studies have been performed and the results have shown that the Mercu1717V digital flat panel detector is substantially equivalent to the predicate devices on the Market (K221714)

Parameter about image quality is equal to or better than predicate device parameter

According to the Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices, the software iRayDR 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:

Intended use, fundamental scientific technology, regulatory requirement, non-clinical performance, labeling, quality-assurance program keep the same with those of predicate device. Additionally, as mentioned in clinical considerations in 'Guidance for the Submission of 510(k)s for Solid State X-ray Imaging Devices',

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, iRay Technology Taicang Ltd. concludes that Mercu1717V is substantially equivalent to predicate device with regards to safety and effectiveness.