CareRay Digital Medical Tehnology Co., Ltd.
℅ Leilei Li
RA Manager
A2-201/B3-501, Biobay, 218 Xinghu Street
SuZhou Industrial Park
Suzhou, Jiangsu 215123
CHINA

February 19, 2021

Re: K202995
Trade/Device Name: X-ray Flat Panel Detectors/CareView 3600RF
Regulation Number: 21 CFR 892.1680
Regulation Name: Stationary x-ray system
Regulatory Class: Class II
Product Code: MQB
Dated: January 15, 2021
Received: January 22, 2021

Dear Leilei Li:

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,

For

Thalia T. Mills, Ph.D.
Director
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)*
K202995

Device Name
X-ray Flat Panel Detectors/CareView 3600RF

Indications for Use *(Describe)*
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.

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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006_510(k) Summary

510(k) Summary

[As required by 21 CFR 807.92]

1. Date Prepared [21 CFR807.92 (a) (1)]

Sep. 28, 2020

2. Submitter's Information [21 CFR807.92 (a) (1)]

Company Name:	CareRay Digital Medical Technology Co., Ltd.
Company Address:	A2-201/B3-501, Biobay, 218 Xinghu Street, Suzhou Industrial Park, Suzhou 215123, P. R. China
Contact Person:	Ms. Li
Phone Number:	(86) 512-86860288
Fax Number:	(86) 512-86860388
E-mail:	ll.li@careray.com

3. Trade Name, Common Name, Classification [21 CFR807.92(a)(2)]

Trade Name:	X-ray Flat Panel Detectors
Model Name:	CareView 3600RF
Classification Name:	Stationary X-ray system
Regulation Number:	21 CFR 892.1680
Regulatory Class:	Class II
Product Code:	MQB

4. Identification of Predicate Device(s) [21 CFR 807.92(a)(3)]

The identified predicates within this submission are as follows:

Manufacturer:	iRay Technology (Shanghai) Ltd.
Trade Name:	Wireless Digital Flat Panel Detector
Model Name:	Mars1417V-PSI
Classification Name:	Stationary X-ray system
Regulation Number:	21 CFR 892.1680

Regulatory Class:	Class II
Product Code:	MQB
FDA 510(k) #:	K161730

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

The CareView 3600RF detector is a class of radiography X-ray flat panel detector that has an imaging area of 867.5mm×433.1mm. The detector communicates by a wired connection (Giga-bit Ethernet communication mode).

The detector functions by intercepting X-ray photons. Then the scintillator emits visible spectrum photons that illuminate an array of photo detectors (a-Si) that create electrical signals. The electrical signals are then digitally converted to display an image on the monitor.

The detector should be connected to a computer and X-ray generator to digitize X-ray images and transfer radiography diagnostics. The x-ray generator, an essential part of a full x-ray system, is not part of the subject medical device.

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

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.

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

Item	**Proposed Device:** **X-ray Flat Panel Detectors**	**Predicate Device:** **Wireless Digital Flat Panel Detector**
510(K) Number	To be assigned	K161730
Model	CareView 3600RF	Mars1417V-PSI
Intended Use	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.	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 product is not intended for mammography or dental applications.
Classification Name	Stationary X-ray system	Stationary X-ray system
Product Code	MQB	MQB

Regulation Number	21 CFR 892.1680	21 CFR 892.1680
Panel	Radiology	Radiology
Class	II	II
X-ray Absorber	GOS Scintillator	GOS Scintillator
Installation Type	Wired	Wireless, Portable
Readout Mechanism	Thin Film Transistor	Thin Film Transistor
Image Matrix Size	5632 × 2816 pixels	2304 × 2800 pixels
Pixel Pitch	154μm	150μm
Effective Imaging Area	867.5 mm × 433.1 mm	355 mm × 434 mm
Grayscale	16 bit	14 bit
Spatial Resolution	3.4 lp/mm	3.4 lp/mm
MTF	75%.....(@ 0.5lp/mm) 50%.....(@ 1lp/mm)	0.75.....(@ 0.5lp/mm)
DQE	(@RQA5, 3.2μGy) 28%.....(@ 0.5lp/mm) 20%.....(@ 1lp/mm)	(@RQA5, 3.2μGy) 0.27.....(@ 0.5lp/mm)
Power Consumption	~50W	Max. 13W
Communications	Gigabit Ethernet	Wired: Gigabit Ethernet Wireless: IEEE 802.11a/b/g/n (2.4 GHz/ 5 GHz)
Imaging Plate	Carbon Fiber Plate	Carbon Fiber Plate
Cooling	Air cooling	Air cooling
Dimensions	916.9mm × 486.4mm × 42.8mm	384mm × 460mm × 15mm
Operation	Temperature: +10 ~ +40℃ Humidity: 30 ~ 75% RH (Non-Condensing) Atmospheric pressure: 700 ~ 1060 hPa Altitude: Max. 3000 meters	Temperature: +5 ~ +35℃ Humidity: 30 ~ 75% RH (Non-Condensing) Atmospheric pressure: 700 ~ 1060 hPa Altitude: Max. 3000 meters
Storage and transportation	Temperature: -20 ~ +55℃ Humidity: 10 ~ 90% RH (Non-Condensing) Atmospheric pressure: 700 ~ 1060 hPa Altitude: Max. 3000 meters	Temperature: -20 ~ +55℃ Humidity: 10 ~ 90% RH (Non-Condensing) Atmospheric pressure: 700 ~ 1060 hPa Altitude: Max. 3000 meters
Software	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 detectors via APIs. In	iRay DR The iRay DR used for getting Digital X-ray radiography images from the flat panel detectors. iRay DR is used to handle the DICOM protocol (DICOM 3.0), iRay DR is responsible for the DR equipment management, acquisition and processing functions, to provides patient

	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.	registration, scanning, image processing, image forwarding, image printing and other functions.
Utilized FDA guidance documents	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. Pediatric Information for X-ray Imaging Device Premarket Notifications 4. Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices 5. Content of Premarket Submissions for Management of Cybersecurity in Medical Devices	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. Pediatric Information for X-ray Imaging Device Premarket Notifications 4. Radio Frequency Wireless Technology in Medical devices 5. Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices 6. Content of Premarket Submissions for Management of Cybersecurity in Medical Devices

8. System requirements to operate with other radiographic system components

The submitted medical device is the CareView 3600RF digital detector. The other x-ray system components referred below are for information purpose only.

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 questions regarding the compatibility issue for

other generators, please contact your distributor or CareRay.

2) Application Program Interface (API) for system integration manufacturer

Peripheral hardware: CareView detector connected via wired communication.

CPU: Intel (R) Core (TM) 2 Duo, 2.93GHz or above

RAM: 6 GB or higher

Hard disk: 80 GB or higher

Monitor: 1280 x 1024 or higher

OS: Windows 7 or Windows 10

Development environment: MS Visual Studio 2005

3) X-ray exposure mode

The synchronous connection mode is the signal transfer mode between the X-ray generator which sends the X-ray and the detector which receives the X-ray.

CareView 3600RF supported typical sync mode contains external sync mode.

The detector can't provide feedback to the generator to terminate the x-ray exposure.

9. Substantial Equivalence [21 CFR 807.92(b) (1) and 807.92(b)(2)]

- Electrical safety and EMC testing

  Electrical, mechanical, environmental safety and performance testing according to IEC/ES 60601-1 was performed, and EMC testing was also conducted in accordance with IEC/EN 60601-1-2. All test results are satisfactory.

- Nonclinical and clinical considerations

  The non-clinical studies have been performed and the results have shown that the CareView 3600RF X-ray flat panel detectors is substantially equivalent to the predicate device on the market (Mars1417V-PSI Wireless Digital Flat Panel Detector, K161730):

  Detective quantum efficiency (DQE), Quantum limited performance, Modulation transfer function (MTF), Effects of aliasing, Sensitivity linearity, Lag(Erasure thoroughness), Change in detection sensitivity, Dose requirement and reciprocity changes, Stability of device characteristics with time, Uniformity of device characteristic, Noise power spectrum(NPS), Spatial resolution, Image Acquisition time, & Black level

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, the CareView 3600RF X-ray flat panel detector is substantially equivalent to predicate device Mars1417V-PSI Wireless

Digital Flat Panel Detector (K161730). Both propose and predicate devices are same in the intended use, the design principle and the applicable standards. Therefore, CareRay Digital Medical Technology Co., Ltd. concludes the CareView 3600RF X-ray flat panel detector is substantially equivalent with the predicate device with regard to safety and effectiveness..