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

August 7, 2020

Re: K201932
Trade/Device Name: X-ray Flat Panel Detectors (CareView 1800Cwe /CareView 1500Cwe)
Regulation Number: 21 CFR 892.1680
Regulation Name: Stationary x-ray system
Regulatory Class: Class II
Product Code: MQB
Dated: July 1, 2020
Received: July 13, 2020

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

510(k) number: K201932

510(k) Summary

510(k) Summary

K201932

[As required by 21 CFR 807.92]

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

July 01, 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
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3. Trade Name, Common Name, Classification [21 CFR807.92(a)(2)]

Trade Name:	X-ray Flat Panel Detectors
Model Name:	CareView 1800Cwe/ CareView 1500Cwe
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:	CareRay Digital Medical Technology Co., Ltd.
Trade Name:	X-ray Flat Panel Detectors
Model Name:	CareView 1800Le
Classification Name:	Stationary X-ray system
Regulation Number:	21 CFR 892.1680

Regulatory Class:	Class II
Product Code:	MQB
FDA 510(k) #:	K193173

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

The CareView 1800Cwe/ CareView 1500Cwe detector is a class of digital X-ray flat panel detector that has an imaging area of 430mm×430mm/430mm×356mm. The detector communicates with wireless and an optional wired communication feature (Giga-bit Ethernet communication mode via connecting the power box).

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.

The software that supports the functions of the digital detector CareView 1800Cwe/ CareView 1500Cwe is unchanged from the predicate. And the API for the digital detector CareView 1800Cwe/ CareView 1500Cwe is the same as that for the predicate device. Besides, there are only minor differences between the firmware for the CareView 1800Cwe/ CareView 1500Cwe and predicate device except to support battery supply and wireless communication.

Generally, CareView 1800Cwe is the same as the cleared product, CareView 1800Le except the wireless function. And CareView 1500Cwe is the same as the cleared product, CareView 1800Le except the wireless function and dimension.

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

The CareView 1800Cwe/ CareView 1500Cwe 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: X-ray Flat Panel Detectors**
510(K) Number	K201932		K193173
Model	CareView 1800Cwe	CareView 1500Cwe	CareView 1800Le

Classification Name	Stationary X-ray system		Stationary X-ray system
Product Code	MQB		MQB
Regulation Number	892.1680		892.1680
Panel	Radiology		Radiology
Class	II		II
X-ray Absorber	CsI Scintillator		CsI Scintillator
Installation Type	Wireless, Cassette		Wired, Cassette
Readout Mechanism	Thin Film Transistor		Thin Film Transistor
Image Matrix Size	3072 × 3072 pixels	3072 × 2560 pixels	3072 × 3072 pixels
Pixel Pitch	140μm		140μm
Effective Imaging Area	430 mm × 430 mm	430 mm × 356 mm	430 mm × 430 mm
Grayscale	16 bit, 65536 grayscale		16 bit, 65536 grayscale
Spatial Resolution	3.57 line pair/mm		3.57 line pair/mm
MTF	~63%.....(@ 1lp/mm) ~35%.....(@ 2lp/mm) ~17%.....(@ 3lp/mm)		≥63%.....(@ 1lp/mm) ≥35%.....(@ 2lp/mm) ≥17%.....(@ 3lp/mm)
DQE	(@RQA5, 27μGy) ~62%.....(@ 0lp/mm) ~45%.....(@ 1lp/mm) ~17%.....(@ 3lp/mm)		(@RQA5, 30μGy) ≥62%.....(@ 0lp/mm) ≥45%.....(@ 1lp/mm) ≥17%.....(@ 3lp/mm)
Rated Power Supply ● Wireless ● Wired	DC +24 V, Max.2 A	DC +24 V, Max.1.5 A	DC +24 V, Max.1 A
	● Powered by the battery ● Powered by the power box using interface cable		● Powered by the power box using interface cable
Wireless communications	IEEE 802.11a/b/g/n (2.4 GHz / 5 GHz)		/
Network interface	Gigabit Ethernet		Gigabit Ethernet
Imaging Plate	Carbon Fiber Plate		Carbon Fiber Plate
Cooling	Air cooling		Air cooling
Dimensions	460 mm × 460 mm × 15 mm	460 mm × 384 × 15 mm	460 mm × 460 mm × 15 mm
Operation	Temperature: +5 ~ +35℃ Humidity: 30 ~ 75% (Non-Condensing) Atmospheric pressure: 700 ~ 1060 hPa		Temperature: +5 ~ +35℃ Humidity: 30 ~ 75% (Non-Condensing) Atmospheric pressure: 700 ~ 1060 hPa
Storage and transportation	Temperature: -20 ~ +55℃ Humidity: 10 ~ 90% (Non-Condensing) Atmospheric pressure: 700 ~ 1060 hPa		Temperature: -20 ~ +55℃ Humidity: 10 ~ 90% (Non-Condensing) Atmospheric pressure: 700 ~ 1060 hPa
API	V4.8.0		V4.8.0
Firmware	V0.96e		V0.96j
Utilized FDA	1. Guidance for the Submission of 510(k)s for		1. Guidance for the

guidance documents	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	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

8. System requirements to operate with other radiographic system components

The submitted medical device is the CareView 1800Cwe/ CareView 1500Cwe 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 XP or 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 1800Cwe/ CareView 1500Cwe supported typical sync mode contains soft sync, manual sync and F^2AED modes.

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 proposed device (CareView 1800Cwe/ CareView 1500Cwe) and predicate device (CareView 1800Le) share most of primary product specifications including intended use, technology, material, and imaging principle, power supply method etc. The only difference is the wireless function and dimension.

  The difference of wireless function and dimension don't affect the technological parameters and clinical images.

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 1800Cwe/ CareView 1500Cwe X-ray flat panel detector is substantially equivalent to predicate device CareView 1800Le(K193173). Both propose and predicate devices are same in the intended use, the design principle, the applicable standards and specification. Some characteristics, for example, wireless function and dimension are different. However the test reports in this submission documents provide demonstration that this difference doesn't raise any new questions of safety and effectiveness. Therefore, CareRay Digital Medical Technology Co.,

Ltd. concludes the CareView 1800Cwe/ CareView 1500Cwe X-ray flat panel detector is substantially equivalent with the predicate device CareView 1800Le(K193173).