



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

December 13, 2019

Re: K193173

Trade/Device Name: X-ray Flat Panel Detectors (CareView 1800Le)
Regulation Number: 21 CFR 892.1680
Regulation Name: Stationary x-ray system
Regulatory Class: Class II
Product Code: MQB
Dated: November 19, 2019
Received: November 22, 2019

Dear Ms. 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

Indications for Use

510(k) Number (if known)

K193173

Device Name

X-ray Flat Panel Detectors (CareView 1800Le)

Indications for Use (Describe)

The CareView 1800Le 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

K193173

510(k) Summary

K193173

[As required by 21 CFR 807.92]

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

Nov. 04, 2019

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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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 1800Le
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 1800L
Classification Name: Stationary X-ray system
Regulation Number: 21 CFR 892.1680

Regulatory Class: Class II
 Product Code: MQB
 FDA 510(k) #: K153492

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

The CareView 1800Le detector is a class of digital X-ray flat panel detector that has an imaging area of 430mm×430mm. The detector communicates by a wired connection (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 1800Le is unchanged from the predicate.

Generally, CareView 1800Le is the same as the cleared product, CareView 1800L except the pixel size. The pixel size of CareView 1800Le is 140 μm, while the CareView 1800L is 154 μm.

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

The CareView 1800Le 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	To be assigned	K153492
Model	CareView 1800Le	CareView 1800L
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	Wired, Cassette	Wired, Cassette

Readout Mechanism	Thin Film Transistor	Thin Film Transistor
Image Matrix Size	3072 x 3072 pixels	2816 x 2816 pixels
Pixel Pitch	140µm	154µm
Effective Imaging Area	430 mm x 430 mm	434 mm x 434 mm
Grayscale	16 bit, 65536 grayscale	16 bit, 65536 grayscale
Spatial Resolution	3.57 line pair/mm	3.3 line pair/mm
MTF	≥63%.....(@ 1lp/mm) ≥35%.....(@ 2lp/mm) ≥17%.....(@ 3lp/mm) ≥10%.....(@ 3.5lp/mm)	~70%.....(@ 1lp/mm) ~40%.....(@ 2lp/mm) ~22%.....(@ 3lp/mm)
DQE	(@RQA5, 30µGy) ≥62%.....(@ 0lp/mm) ≥45%.....(@ 1lp/mm) ≥17%.....(@ 3lp/mm) ≥10%.....(@ 3.5lp/mm)	(@RQA5, 30µGy) ~65%.....(@ 0lp/mm) ~20%.....(@ 3lp/mm)
Rated Power Supply	DC +24 V, Max.1 A Powered by the power box using interface cable	DC +24 V, Max.1 A Powered by the power box using interface cable
Communications	Gigabit Ethernet	Gigabit Ethernet
Imaging Plate	Carbon Fiber Plate	Carbon Fiber Plate
Cooling	Air cooling	Air cooling
Dimensions	460 mm x 460 mm x 15 mm	460 mm x 460 mm x 15 mm
Operation	Temperature: +5 ~ +35°C Humidity: 30 ~ 75% (Non-Condensing) Atmospheric pressure: 700 ~ 1060 hPa	Temperature: +5 ~ +35°C Humidity: 30 ~ 75% (Non-Condensing) Atmospheric pressure: 700 ~ 1060 hPa
Storage and transportation	Temperature: -20 ~ +55°C Humidity: 10 ~ 90% (Non-Condensing) Atmospheric pressure: 700 ~ 1060 hPa	Temperature: -20 ~ +55°C Humidity: 10 ~ 90% (Non-Condensing) Atmospheric pressure: 700 ~ 1060 hPa

8. System requirements to operate with other radiographic system components

The submitted medical device is the CareView 1800Le 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 1800Le supported typical sync mode contains external sync, soft sync, manual sync and auto sync containing FFAED 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 proposed device (CareView 1800Le) and predicate device (CareView 1800L) share most of primary product specifications including intended use, technology, material, and imaging principle, power supply method etc. The only difference is the pixel size. While the predicate device pixel size is 154 μm , the proposed device pixel size is 140 μm .

The difference of pixel size doesn'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 1800Le X-ray flat panel detector is substantially equivalent to predicate device CareView 1800L(K153492).

Both propose and predicate devices are same in the intended use, the design principle, the applicable standards and specification. Some characteristics, for example, pixel size is 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 1800Le X-ray flat panel detector is substantially equivalent with the predicate device CareView 1800L (K153492).