DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

January 8, 2016

CareRay Digital Medical Systems Co., Ltd.
% Ms. Leilei Li
Engineer, R&D Department
A2-201/B3-501, Biobay, 218 Xinghu Street, SuZhou Industrial Park
SuZhou, Jiangsu 215123
CHINA

Re: K153492
Trade/Device Name: CareView 1800L X-ray Flat Panel Detectors
Regulation Number: 21 CFR 892.1680
Regulation Name: Stationary x-ray system
Regulatory Class: II
Product Code: MQB
Dated: December 01, 2015
Received: December 04, 2015

Dear Ms. Li:

This letter corrects our substantially equivalent letter of December 24, 2015.

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. 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); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

For

Robert Ochs, Ph.D.
Director
Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K153492

Device Name
CareView 1800L X-ray Flat Panel Detectors

Indications for Use *(Describe)*
The CareView 1800L 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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510(k) Summary

510(k) Summary

[As required by 21 CFR 807.92]

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

Dec. 01, 2015

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

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

Regulatory Class:	Class II
Product Code:	MQB
FDA 510(k) #:	K153058

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

CareView 1800L is a kind of cassette size digital X-ray flat panel detectors which have 434mm×434mm imaging area. The device communicates by wired communication feature (Giga-bit Ethernet communication mode by connecting the power box).

The device intercepts X-ray photons and then the scintillator emits visible spectrum photons that illuminate an array of photo detectors (a-Si) that create electrical signals. After the electrical signals are generated, it is converted to a digital value and an image will be displayed on the monitor.

The detector should be integrated with an operating PC and an X-ray generator to utilize as digitalizing X-ray images and transfer for radiography diagnostic.

Generally, CareView 1800L is the same as the cleared product, CareView 1500L except the dimension. The dimension of CareView 1800L is 460mm × 460mm × 15mm, while the CareView 1500L is 384mm × 460mm × 15mm.

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

The CareView 1800L 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	K153058
Model	CareView 1800L	CareView 1500L
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	2816 × 2816 pixels	2304 × 2816 pixels
Pixel Pitch	154μm	154μm
Effective Imaging Area	434 mm × 434 mm	355 mm × 434 mm
Grayscale	16 bit, 65536 grayscale	16 bit, 65536 grayscale
Spatial Resolution	Min. 3.3 line pair/mm	Min. 3.3 line pair/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
Power Consumption	Max. 24 W	Max. 24 W
Communications	Gigabit Ethernet	Gigabit Ethernet
Imaging Plate	Carbon Fiber Plate	Carbon Fiber Plate
Cooling	Air cooling	Air cooling
Dimensions	460 mm × 460 mm × 15 mm	384 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

8. System requirements to operate with other radiographic system components

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: 2 GB or higher

Hard disk: 160 GB or higher

Monitor: 1280 x 1024 or higher

OS: Windows XP or Windows 7

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 1800L 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 1800L) and predicate device (CareView 1500L) share most of primary product specifications including intended use, technology, material, and imaging principle, power supply method etc. The only difference is the dimension. While the predicate device dimension is 384mm × 460mm × 15mm, the proposed device dimension is 460mm × 460mm × 15mm.

  The difference of dimension 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 1800L X-ray flat panel detector is substantially equivalent to predicate device CareView 1500L(K153058). Both propose and predicate devices are same in the intended use, the design principle, the applicable standards and specification. Some characteristics, for example, dimension 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 System Co., Ltd. concludes the CareView 1800L X-ray flat panel detector is substantially equivalent with the predicate device CareView 1500L (K153058).