December 30, 2022

CareRay Digital Medical Technology Co., Ltd.
Xu Wei
Manager
A2-201/B3-501, Biobay, 218 Xinghu Street
SuZhou Industrial Park
Suzhou, Jiangsu 215123
CHINA

Re: K223687
Trade/Device Name: X-ray Flat Panel Detectors (EverestView 4343X)
Regulation Number: 21 CFR 892.1680
Regulation Name: Stationary x-ray system
Regulatory Class: Class II
Product Code: MQB, JAA
Dated: December 9, 2022
Received: December 9, 2022

Dear Xu Wei:

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,

Esther O. Akinnagbe-zusterzeel -S

Digitally signed by Esther O. Akinnagbe-zusterzeel -S
Date: 2022.12.30 12:35:26 -05'00'

for Lu Jiang, 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)*
K223687

Device Name
X-ray Flat Panel Detectors (EverestView 4343X)

Indications for Use *(Describe)*
The 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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(k) Summary

K223687

[As required by 21 CFR 807.92]

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

November 22, 2022

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:	Mr. Xu
Phone Number:	(86) 512-86860288
Fax Number:	(86) 512-86860388
E-mail:	Wei.xu@careray.com

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

Trade Name:	X-ray Flat Panel Detectors
Model Name:	EverestView 4343X
Classification Name:	Stationary X-ray system
Regulation Number:	21 CFR 892.1680
Regulatory Class:	Class II
Product Code:	MQB,JAA

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

The identified primary predicates within this submission are as follows:

Manufacturer:	CareRay Digital Medical Technology Co., Ltd.
Trade Name:	X-ray Flat Panel Detectors
Model Name:	CareView 1800RF
Classification Name:	Stationary X-ray system

Regulation Number:	21 CFR 892.1680
Regulatory Class:	Class II
Product Code:	MQB,JAA
FDA 510(k) #:	K221549

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

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 for transfer of diagnostic images. The functions of the EverestView 4343X are supported by software and the software is of Moderate level of concern. The main function of software is image acquisition and transfer and it doesn't have functions of image post-processing. The detectors can be used for dynamic imaging (fluoroscopy) that is same as Predicate Device.

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

The 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)]

Comparison with the predicate device

Item	Proposed Device: X-ray Flat Panel Detectors	Predicate Device : X-ray Flat Panel Detectors
510(K) Number	To be assigned	K221549
Model	EverestView 4343X	CareView 1800RF
Intended Use	The 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.	The 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.
Classification Name	Stationary X-ray system	Stationary X-ray system
Product Code	MQB,JAA	MQB,JAA
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	4302 ×4302 pixels	2816 × 2816 pixels
Pixel Pitch	100 μm	154μm
Effective Imaging Area	430 mm ×430 mm	434 mm × 434 mm
Grayscale	16 bit, 65536 grayscale	16 bit, 65536 grayscale
Spatial Resolution	5.0 line pair/mm	3.3 line pair/mm
MTF	≥65.....(@ 1lp/mm) ≥20.....(@ 3lp/mm) ≥7.....(@ 5p/mm)	≥60%.....(@ 1lp/mm) ≥30%.....(@ 2lp/mm) ≥17%.....(@ 3lp/mm)
DQE	(@RQA5, 2μGy) ≥62.....(@ 0lp/mm) ≥30.....(@ 3lp/mm) ≥11.....(@ 5lp/mm)	(@RQA5, 2μGy) ≥55%.....(@ 1lp/mm) ≥20%.....(@ 3lp/mm)
Pixel matrix	100μm:4302×4302 (1x1 binning); 200μm: 2150×2150 (2x2 binning) 400μm: 1074×1074 (3x3 binning)	154μm: 2816×2816 (1x1 binning); 308μm: 1408×1408 (2x2 binning) 462μm: 896×896 (3x3 binning)
Frame rate	5fps@2150×2150 20fps@1074×1074	4fps@2816×2816 15fps@1408×1408

		25fps@896×896
Rated Power Supply	DC 24 V, Max. 2 A	DC 24 V, Max.1.25 A
Network interface	Gigabit Ethernet	Gigabit Ethernet
Imaging Plate	Carbon Fiber Plate	Carbon Fiber Plate
Cooling	Air cooling	Air cooling
Dimensions	460mm ×460mm ×15mm	460mm × 460mm × 28mm
Operation	Temperature: +10 ~ +40℃ Humidity: 30 ~ 75% (Non-Condensing) Atmospheric pressure: 700 ~ 1060 hPa	Temperature: +10 ~ +40℃ 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
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. 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	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 X-ray Flat Panel 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.

The detectors support 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 proposed devices and predicate device 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. Clinical images are not necessary for the current submission. Successful results of bench testing should be sufficient to show substantial equivalence for the subject device.

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 proposed devices are substantially equivalent to predicate device CareView 1800RF X-ray flat panel detectors (K221549). 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 proposed devices are substantially equivalent with the predicate device with regard to safety and effectiveness.