Carestream Health, Inc.
℅ Gina Maiolo
Regulatory Affairs Manager
150 Verona Street
ROCHESTER NY 14608

December 2, 2020

Re: K203159
Trade/Device Name: Lux 35 Detector
Regulation Number: 21 CFR 892.1680
Regulation Name: Stationary x-ray system
Regulatory Class: Class II
Product Code: MQB
Dated: October 30, 2020
Received: November 2, 2020

Dear Gina Maiolo:

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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K203159

Device Name
Lux 35 Detector

Indications for Use *(Describe)*
"The device is intended to capture for display radiographic images of human anatomy including both pediatric and adult patients. The device is intended for use in general projection radiographic applications wherever conventional screen-film systems or CR systems may be used. Excluded from the indications for use are mammography, fluoroscopy, and angiography 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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K203159

510(k) Summary

510(k) Owner:
Carestream Health, Inc
150 Verona Street
Rochester, New York 14608
Contact: Gina Maiolo
Regulatory Affairs Manager
585.627.6543

Carestream Health, Inc. is submitting this Special 510(k) premarket notification for modifications to the DRX Plus 3543 Flat Panel Detector. Caresteam believes the modified DRX Plus 3543C Flat Panel Detector is substantially equivalent to the cleared device (K150766).

Date Summary Prepared: August 15 2020		
	Predicate	**Subject**
Device Trade Name	DRX Plus 3543 Detector	Lux 35 Detector
Device Common Name	Digital Flat Panel Detector	Digital Flat Panel Detector
Classification Name	Solid State X-Ray Imager (Flat Panel/Digital Imager)	Solid State X-Ray Imager (Flat Panel/Digital Imager)
Device Class	Class II	Class II
Device Code	MQB	MQB
Regulation Number	21 CFR 892.1680	21 CFR 892.1680
Predicate Device	DRX Plus 3543GOS Flat Panel Detector	DRX Plus 3543C Flat Panel Detector

Indications for Use

"The device is intended to capture for display radiographic images of human anatomy including both pediatric and adult patients. The device is intended for use in general projection radiographic applications wherever conventional screen-film systems or CR systems may be used. Excluded from the indications for use are mammography, fluoroscopy, and angiography applications."

In addition, the indications for use of the modified device, as described in labeling does not change as a result of the device modifications.

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Device Description

The modified DRX Plus 3543C is a scintillator-photodetector device (Solid State X-ray Imager) utilizing an amorphous silicon flat panel image sensor. The modified detector is redesigned with the intent to reduce weight and increase durability, while utilizing a non-glass substrate material and cesium iodide scintillator. The modified detector, like the predicate is designed to interact with Carestream's DRX-1 System (K090318).

The modified DRX Plus 3543C Detector, like the predicate, creates a digital image from the x-rays incident on the input surface during an x-ray exposure. The flat panel imager absorbs incident x-rays and converts the energy into visible light photons. These light photons are converted into electrical charge and stored in structures called "pixels." The digital value in each pixel of the image is directly related to the intensity of the incident x-ray flux at that particular location on the surface of the detector. Image acquisition software is used to correct the digital image for defective pixels and lines on the detector, perform gain and offset correction and generate sub-sampled preview images

The modified and predicate are essentially the same as they are both digital x-ray flat panel scintillator-photodetector devices (Solid State X-ray Imagers) utilizing an amorphous silicon flat panel image sensor. The predicate and modified are both DRX Plus 3543 flat panel detectors, the difference is that the modified device utilizes a cesium iodide (Csi) scintillator, whereas the predicate utilizes gadolinium oxysulfide (GOS). The modified device official product name is marketed as "Lux 35 Detector." Both flat panels operate primarily in a wireless state, using a battery for power and allows wireless communication for control and data transmission. This eliminates the need for cables that can hinder efficient workflow. The detectors have the ability to communicate via a wired ("tethered") connection to the console, if desired

Technological Characteristics

The modified detector is substantially equivalent to the predicate device currently cleared on the market (K150766) and uses the same fundamental scientific technology as the predicate device.
The detectors are both digital x-ray flat panel scintillator-photodetector devices (Solid State X-ray Imager) utilizing an amorphous silicon flat panel image sensor. The predicate and modified are both DRX Plus 3543 flat panel detectors, the main difference is that the modified device utilizes a cesium iodide (Csi) scintillator and non-glass substrate whereas the predicate utilizes gadolinium oxysulfide (GOS) and a glass substrate. The modified device official product name is marketed as Lux 35 Detector.

Both flat panels operate primarily in a wireless state, using a battery for power and allows wireless communication for control and data transmission. This eliminates the need for cables that can hinder efficient workflow. The detectors have the ability to communicate via a wired ("tethered") connection to the console, if desired. The modified detector is designed to interact with Carestream's existing acquisition software that resides on the legally marketed Carestream DRX-1 System (K090318). The predicate device (DRX Plus 3543) has clearance with DRX-1 under K150766. Additionally, the DRX-1 System has clearance for the following Carestream detectors:

- K130464 (DRX 2530C)
- K183425 (DRX Plus 2530 Detector)
- K150766 (DRX 3543 Plus Detectors)

Carestream has obtained previous detector clearances for use with DRX-1, as listed above.
This submission is for the clearance of the modified digital flat panel detector only.

After images are captured with the digital flat panel detector and can be communicated to the DRX-1 System console. The DRX-1 System contains Image Eclipse Processing Software II to allow rendering of the images. The image is processed and transformed into data for viewing and then put into DICOM format for output. Image Eclipse Processing Software II has been cleared for use (K180809) with previous Carestream DRX Plus 2530C under K183425.

The image acquisition software corrects the digital image for defective pixels and lines on the detector, perform gain and offset correction, and generate sub-sampled preview images. The image acquisition software that resides on the DRX-1 System console will be replaced with Image View Software. The ImageView Software has obtained several FDA clearances for use with Carestream Digital Radiography Systems used with the Carestream flat panels:

- K163203 – DRX Evolution System with Image View Software
- K191205 – DRX-Mobile Revolution System with Image View Software
- K201373 – DRX-Compass

Summary of Guidance & Standards Compliance

- Content of Premarket Submissions for Management of Cybersecurity in Medical Devices Guidance for Industry and Food and Drug Administration Staff Document Issued on: October 2, 2014

- Pediatric Information for X-ray Imaging Device Premarket Notifications Guidance for Industry and Food and Drug Administration Staff Document issued on November 28, 2017

- Guidance for the Submission of 510(k)s for Solid State X-ray Imaging Devices Guidance for Industry and Food and Drug Administration Staff Document issued on: September 1, 2016

- Guidance for Industry and FDA Staff Guidance for the Content of Premarket Submissions for Software contained in Medical Devices, Document issued on: May 11, 2005 Medical Devices, Document issued on: May 11, 2005

- Guidance for Industry and FDA Radio Frequency Wireless Technology in Medical devices Guidance for Industry and Food and Drug Administration Staff Document issued on: August 14, 2013 Document issued on: August 14, 2013

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Applicable Standards:

- ANSI AAMI ES60601-1:2005/(R)2012 and A1:2012, C1:2009/(R)2012 and A2:2010/(R)2012 (Consolidated Text) Medical electrical equipment - Part 1: General requirements for basic safety and essential performance (IEC 60601-1:2005, MOD)

- ANSI C95 1-1999 Standard for Safety Levels with Respect to Human Exposure to Radio Frequency Electromagnetic Fields 3KHz to 300GHz

- IEC 60601-1-2 Edition 4.0 2014-02 Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests

- FCC Radio Frequency Devices, Sub C (International Radiators) Sub E (Unlicensed Nationale Infrastructure Devices, 209(a) (Radiated Emissions) 30-1000MHz), 15.205 (Restricted Bands),15.203 (Antenna Requirements)

- ISO 14971:2019 Medical Devices- Application of Risk Management to medical devices

- ISO 10993-1 Fourth edition 2009-10-15 Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process

Summary of Non-Clinical Testing

Clinical testing was not required to establish substantial equivalence. Bench testing was sufficient to assess the device safety and effectiveness. The performance of the modified device DRX Plus 3543C (Lux 35) detector was evaluated in non-clinical (bench) testing using a Phantom Image Study.
A technical analysis (non-diagnostic) of image quality attributes such as detail, sharpness, noise and appearance of artifacts were compared for each image.
Greater than 84% of all responses were rated 0 or higher in favor of the modified DRX Plus 3543C panel. All ratings for the attributes (detail contrast, sharpness and noise) were significantly greater than 0 indicating that the modified DRX Plus 3543C images were equivalent to just noticeably better than the predicate images.

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A comparison chart provides similarities and differences between the modified and predicate device.

Comparison	Predicate DRX Plus 3543 Digital Flat Panel Detector (K150766)	Modified DRX Plus 3543C (Lux 35) Digital Flat Panel Detector	Risk Conclusion
Indications for Use	The device is intended to capture for display radiographic images of human anatomy including both pediatric and adult patients. The device is intended for use in general projection radiographic applications wherever conventional screen-film systems or CR systems may be used. Excluded from the indications for use are mammography, fluoroscopy, and angiography applications	*Same	Device name change does not impact indications for use and/or safety and effectiveness
Image Processing Software	Eclipse Image Software (K060137)	Eclipse Image Software II (K180809)	Predicate software used a 4-frequency band decomposition method, the modified device uses a 4-10 frequency band decomposition. Differences do not impact indications for use or safety and/or effectiveness
Substrate	Glass	Glass reinforced epoxy laminate	Only the material of the substrate has changed. No change to device functionality/operation. Does not impact image quality, safety and/or effectiveness
X-ray Scintillator Material	Gadolinium Oxysulfide (GOS)	Cesium Iodide (CsI)	Differences in detector material does not impact safety and/or effectiveness
DQE	DQE 26% (RQA-5, 1 cycle/mm, 3.1 µGy)	DQE 55% (RQA-5, 1 cycle/mm, 2.5 µGy)	Improved image quality
MTF	MTF 54% (RQA-5, 1 cycle/mm)	MTF 62% (RQA-5, 1 cycle/mm)	Improved image quality
Detector Weight	6.75 lbs	4.6 lbs	Difference in detector weight does not impact safety and/or effectiveness
Appearance Characteristics	Squared edges	Rounded edges Improved LEDs New Display GUI New Finger Grips	Differences in detector characteristics do not impact safety and/or effectiveness
Image Capture Area (usable pixel area)	35cm x 42.1cm	*Same	No new risks
Pixel Pitch	139 microns	*Same	No new risks

Workstation Console Software	DirectView Software	ImageView Software	The change in software application does not change the detector operation. It is a replacement software limited to GUI changes / Ease of Use. Changes to do not impact safety and/or effectiveness of detectors

Conclusion

- The image quality of the modified device is at least as good as or better than that of the predicate device.
- Results of non-clinical testing demonstrate that the modified device is as safe and as effective as the predicate device.
- The intended use remains unchanged.
- The fundamental scientific technology of the modified device is the same and is substantially equivalent to the predicate.
- The comparison chart demonstrates that the characteristics are primarily the same.