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

February 8, 2019

Re: K183245
Trade/Device Name: Carestream DRX-1 System with DRX Plus 2530 Detectors
Regulation Number: 21 CFR 892.1680
Regulation Name: Stationary x-ray system
Regulatory Class: Class II
Product Code: MQB
Dated: January 14, 2019
Received: January 17, 2019

Dear Ms. 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); 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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Michael D. O'Hara 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K183245

Device Name
Carestream DRX-1 System with DRX Plus 2530 Detectors

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

Carestream

"510(k) Summary"

510(k) Owner Name:	Carestream Health, Inc.
510(k) Owner Address:	150 Verona Street Rochester, New York 14608
510(k) Owner Phone:	585 627-6543
510(k) Owner Fax:	585 627-8802
Contact Person & Info:	Gina Maiolo Regulatory Affairs Manager, US&C gina.maiolo@carestream.com 585-627-6543
Date Summary Prepared:	February 6, 2019
Device Trade Name:	Carestream DRX-1 System with DRX Plus 2530 Detectors
510(k) No.:	K183245
Device Common Name:	Flat Panel Digital Imager
Classification Name:	Stationary x-ray system
Device Class:	Class II
Device Code:	MQB
Regulation Number:	21 CFR 892.1680
Predicate Device:	Carestream DRX-1 System (with DRX Plus 3543 Detectors)
Manufactured by:	Carestream Health, Inc.
510(k) No.:	K150766 (June 24, 2015)
Regulation Number:	21 CFR 892.1680
Classification Name:	Stationary x-ray system
Primary Product Code:	MQB

Device Description:

The Carestream DRX-1 System is a diagnostic imaging system utilizing digital radiography (DR) technology that is used with diagnostic x-ray systems. The system consists of the Carestream DRX-1 System Console (operator console), flat panel digital imager (detector), and optional tether interface box. The system can be configured to register and use any of the two new DRX Plus 2530 and DRX Plus 2530C Detectors. Images captured with a flat panel digital detector can be communicated to the operator console via tethered or wireless connection.

Indications for Use / Intended Use:

The Indications for Use for the device, as described in its labeling, are:

"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."

The intended use for this device, as determined by descriptions and the proposed labeling contained in this submission, is similar to the Indications for Use statement provided above. The Carestream DRX-1 System with DRX Plus 2530 and DRX Plus 2530C Detectors is a diagnostic imaging system utilizing digital radiography (DR) technology that is used to capture x-rays for diagnostic procedures. We believe that the Carestream DRX-1 System with DRX Plus 2530 and DRX Plus 2530C Detectors and the predicate device have the same intended use.

The Indications for Use for the subject device is the same as for the predicate device and the intended use remains unchanged. Any variation in features or technical specifications have been identified and addressed through testing (described below) to support a substantial equivalence determination.

Comparison of Technological Characteristics:

Based upon information provided within this submission, we believe that the Carestream DRX-1 System with DRX Plus 2530 and DRX Plus 2530C Detectors is substantially equivalent to the legally marketed Carestream DRX-1 System with the DRX Plus 3543 Detectors (predicate device) (K150766). Both the currently marketed DRX Plus 3543 Detectors and the new DRX Plus 2530 and DRX Plus 2530C Detectors are used in combination with the image processing software (Eclipse II; K180809) and user interface resident on the DRX-1 System Console component of the Carestream DRX-1 System. The system is used to directly capture conventional projected x-rays to generate digital images, regardless of which detector is being used. An image can be displayed on a preview monitor for viewing with any of the detectors. The system can transmit diagnostic images through a digital network for diagnostic viewing and printing regardless of which detector is used.

The predicate (DRX Plus 3543) detector shares similar design specifications except for the smaller physical size of the detector (25cm X 30cm) and the smaller pixel pitch of (98 X 98 microns) for the DRX Plus 2530 detectors versus (139 X 139 microns) for the DRX Plus 3543 detector.

The predicate device electronics contained separate circuit boards for the embedded controller, power, radio and image boards. The subject device electronics were redesigned to combine these into an All-in-One (AIO) board. In addition, the subject device has an updated readout integrated circuit (ROIC) on the chip on flex (COF). This is the next generation ROIC designed to produce lower noise and higher resolution images. Reuse of the DRX Plus electronics architecture allows for the reuse of the mature and field tested

embedded firmware from the predicate device. Reliability and performance improvements have resulted from this design change included in the subject device.

Both the predicate device and the subject device have housings constructed of aluminum. The predicate device contains a deep dish aluminum housing while the subject device contains an aluminum picture frame design. The change from the deep dish to the picture frame design was a necessary improvement to allow the service engineers full access to the back of the smaller sized detector. The design improvement has no impact to image quality or performance.

Discussion of Testing:

The performance characteristics and operation / usability of the Carestream DRX-1 System with DRX Plus 2530 and DRX Plus 25303C Detectors were evaluated in clinical and non-clinical (bench) testing in accordance with FDA guidance document *"Guidance for the Submission of 510(k)'s for Solid State Imaging Devices"*.

Non-clinical (bench) test results have demonstrated that the device conforms to its specifications. Acceptance criteria were determined based on desired performance with respect to image quality, intended use, workflow related performance, shipping performance, and general functionality and reliability, including both hardware and software requirements. Predefined acceptance criteria were met and demonstrated that the device is as safe, as effective, and performs as well as or better than the predicate device; therefore supporting a substantial equivalence determination. Acceptance criteria were identified for weight, pixel size, resolution, pixel pitch, total pixel area, usable pixel area, MTF (at various spatial resolutions), DQE (at various spatial resolutions), sensitivity, ghosting, boot-up time, operating temperature, exposure latitude, signal uniformity, and dark noise (ADC). Predefined acceptance criteria were met and demonstrated that the device is as safe, as effective, and performs as well as or better than the predicate device.

Additionally, a clinical study was performed to investigate the imaging performance of the Carestream DRX Plus 2530 Detector and the DRX Plus 2530C Detector (referred to as the "investigational devices within the clinical documentation") as compared to the currently marketed Carestream DRX Plus 3543 Detector (GOS) **[**K150766 (referred to as the "predicate device")]. The study was designed in accordance with the FDA Guidance titled "Guidance for the Submission of 510(k)'s for Solid State X-ray Imaging Devices".

The predicate and subject devices were used for image capture at the University of Rochester Medical Center located in Rochester, NY. Adult cadavers (2) were used to perform triplicate acquisitions using the subject devices vs. the predicate device. One-hundred and sixty two (162) acquired images (cadaver and pediatric phantom) were included in this reader study. The cadaver images targeted exam types such as facial bones, nasal bones, skull, C-Spine, shoulder, clavicle, hip and extremity radiographs. Pediatric phantom images targeted exam types such as the chest and extremities. The images were acquired according to clinical protocol (AF3458), and were used to confirm diagnostic image quality using a Radlex rating scale. The images were evaluated by

three (3) board certified radiologists using a graduated 4 point scale based on diagnostic image quality.

The mean RadLex rating for the predicate and both subject devices are of Diagnostic (3) image quality and show very little variability between devices. 98% of the DRX Plus 2530 Detector RadLex rating responses are rated Diagnostic (3) or Exemplary (4). 96% of the DRX Plus 2530C Detector RadLex rating responses are rated Diagnostic (3) or Exemplary (4). In direct comparison to the predicate 71% of the DRX Plus 2530 Detector RadLex rating responses and 68% of the DRX Plus 2530C Detector RadLex rating responses are equivalent to the predicate or favor the subject device.

The two-sample equivalence tests yield results that confirm the equivalence between the mean ratings of the subject devices to the predicate as well as equivalence in either beam detect mode ("On" and "Off").

Summary:
The statistical test results and graphical summaries demonstrate the DRX Plus 2530 Detector and DRX Plus 2530C Detector deliver quality images that are equivalent in diagnostic quality compared with images obtained using a commercially available predicate device.

Conclusion:

In conclusion, the new detectors are equivalent to the DRX Plus 3543 Detectors in all applicable parameters recommended by the *"Guidance for the Submission of 510(k)'s for Solid State Imaging Devices"*. Image quality parameters such as DQE, sensitivity, and MTF of the DRX Plus 2530 and DRX Plus 2530C Detectors demonstrate this. The tests used to determine these parameters were performed using industry standards.

The new detectors have been tested to conform to applicable existing specifications of the predicate DRX Plus 3543 Detectors. Quality Assurance tests with traceable links to design inputs were performed to verify conformance to specifications. In addition, tests were included to confirm mitigation of risks identified in an extensive product hazard risk analysis based on results of a Failure Mode Effects Analysis.