March 12, 2024

Carestream Health, Inc.
℅ Robert Faust
Senior Regulatory Affairs Manager
150 Verona Street
ROCHESTER, NY 14608

Re: K233381
Trade/Device Name: DRX-Evolution Plus System
Regulation Number: 21 CFR 892.1680
Regulation Name: Stationary X-Ray System
Regulatory Class: Class II
Product Code: KPR
Dated: February 2, 2024
Received: February 5, 2024

Dear Mr. Faust:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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 Smita Kakar

Lu Jiang
Assistant Director
Diagnostic X-Ray Systems Team
DHT8B: Division of Radiologic 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)*
K233381

Device Name
DRX-Evolution Plus

Indications for Use *(Describe)*

The DRX-Evolution Plus is a permanently installed diagnostic x-ray system for general radiographic x-ray imaging. This device is a permanently installed diagnostic x-ray system for general radiographic x-ray imaging. This device also supports Dual Energy chest imaging. The Dual Energy feature is not to be used for imaging pediatric patients.

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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Carestream

K233381 **510(k) Summary**

510(k) Owner Name: Carestream Health, Inc.
510(k) Owner Address: 150 Verona Street
Rochester, NY, 14608

510(k) Owner Phone: 603-686-2054
510(k) Owner Fax: 585-627-8802

Contact Person & Info: Robert Faust
Senior Regulatory Affairs Manager
robert.faust@carestream.com
603-686-2054

Date Summary Prepared: March 5, 2024

Predicate
510(k) Submitter: Carestream Health, Inc.
510(k) Number: K190330
Trade Name: DRX-Evolution Plus
Device: System, X-Ray, Stationary
Regulation Description: Stationary x-ray system
Review Panel: Radiology
Product Code: KPR
Regulation Number: 21 CFR 892.1680
Device Class: II

Subject Device
510(k) Submitter: Carestream Health, Inc.
Trade Name: DRX-Evolution Plus
Device: System, X-Ray, Stationary
Regulation Description: Stationary x-ray system
Review Panel: Radiology
Product Code: KPR
Regulation Number: 21 CFR 892.1680
Device Class: II

Indications for Use / Intended Use:

The DRX-Evolution Plus is a permanently installed diagnostic x-ray system for general radiographic x-ray imaging. This device is a permanently installed diagnostic x-ray system for general radiographic x-ray imaging. This device also supports Dual Energy chest imaging. The Dual Energy feature is not to be used for imaging pediatric patients.

Device Description:

The DRX-Evolution Plus is a general purpose x-ray system used for acquiring radiographic images of various portions of the human body. The system consists of a combination of components including various

models of high voltage x-ray generators, control panels or workstation computers, various models of patient support tables, wall-mounted image receptors/detectors for upright imaging, various models of tube support devices, x-ray tube, and collimator (beam-limiting device). In addition to general radiography applications, the system also includes the optional Dual Energy functionality.
The DRX-Evolution Plus can be used with digital radiography (DR) and computed radiography (CR) receptors.

"Smart" Features are added to the DRX-Evolution Plus system to provide remote exam set-up capabilities for existing functions of the DRX-Evolution Plus system. These remote capabilities simplify exam set up and improve workflow for the operator while preparing for the patient exposure. The "smart" features, described below, are designed to reduce the technologist's manual tasks and to speed up workflow for existing features of the system. Implementation of these features does not change the intended use of the system and does not affect the Dual Energy functionality.

- **Real-time Video Assistance:**
  The subject DRX-Evolution Plus uses the real-time video output of the visual auxiliary components (cameras) to display the patient on the user interface to assist the operator in guiding the patient to adjust the position and posture, and assisting adjustment X-ray field, X-ray gantry position, etc.
- **Long Length Imaging (LLI):**
  The subject DRX-Evolution Plus provides the capability for the operator to select LLI parameters on the user interface without needing to physically be in the exam room.
- **Collimation:**
  The subject DRX-Evolution Plus allows the operator to collimate the intended location of the x-ray beam remotely from the user interface.
- **Patient Picture:**
  The subject DRX-Evolution Plus can now use cameras to take a picture of the patient to be delivered with the x-ray image.

In addition to the enhanced workflow features described above, additional digital detectors have been (bench) tested and integrated for use with the DRX-Evolution Plus system:

Detector Name	510(k) Number	Pixel Size	Pixel Matrix	Scintillator Material	Can be used for Dual Energy
DRX Plus 2530C	K183245	98µm	3016 x 2504	Cesium Iodide	No
Focus 35 HD	K213646	100µm	3500 x 4300	Cesium Iodide	No
Focus 43 HD	K213529	100µm	4267 x 4267	Cesium Iodide	No
DRX-LC	K220536	139µm	3064 x 8696	Cesium Iodide	No
Lux 35	K203159	139µm	2560 x 3072	Cesium Iodide	Yes

Table 1

Substantial Equivalence:

Based upon information provided within this submission, we believe that the subject DRX-Evolution Plus, is substantially equivalent to the legally marketed DRX-Evolution Plus (predicate device).
In accordance with FDA Final Guidance "The 510(k) Program: Evaluating Substantial Equivalence in Premarket Notifications [510(k)]" issued July 28, 2014, the critical decision points outlined in the proposed 510(k) Decision-Making Flowchart in Appendix A have been considered. The proposed predicate device, DRX-Evolution Plus, has been found substantially equivalent by FDA through the 510(k) process and is

legally marketed. The Indications for Use for the subject device are identical to the predicate indications for use.

According to ISO 14971 Risk Management methodology, any new risks that may raise additional questions of safety and performance have been identified and mitigated as far as possible. There have been no changes to risk control measures in the current product risk analysis. Testing to recognized FDA consensus standards and internal non-clinical (bench) testing support substantial equivalence.

Comparison of Technological Characteristics
A comparison chart (Table 2) provides the similarities and differences between the subject and predicate devices.

Property	**Predicate Device** DRX-Evolution Plus K190330	**Subject Device** DRX-Evolution Plus K233381
Digital Radiography Imaging Devices (Detector)	DRX Plus 3543 and 3543C Detectors DRX Plus 4343 and 4343C Detectors	Supports the same detectors as the predicate devices and the additional detectors listed below: DRX Plus 2530C (K183245) Focus HD 35 (K213646) Focus HD 43 (K213529) LUX 35 (K203159) DRX-LC (K230059)
Application System Software	Image View Software	Same
Electrical Safety	IEC 60601-1 IEC 60601-1-2 IEC 60601-1-3 IEC 60601-2-54	Same
Visualization of the Patient	Physically Visualize the Patient	Real-time Video Assistance from User Interface
LLI Upper and Lower Limit Selection	LLI Selection on Tube Head	LLI Selection from User Interface
Collimation	Manual / IR Remote Control Collimation	Collimation from User Interface
Patient Picture	Not Available	Patient Picture from User Interface

Table 2: Comparison Chart

Summary of Non-Clinical Performance and Safety Testing and Data:

Non-clinical testing such as standards testing are the same as that of the predicate. The verification and validation testing of the subject device demonstrates that the subject device performs as well as the predicate and is substantially equivalent. 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.

DRX-Evolution Plus complies with and/or was tested in accordance with the following FDA and International Standards:

- AAMI ES60601-1:2005 +C1:A2: 2012 Medical electrical equipment - Part 1: General requirements for basic safety and essential performance (IEC 60601-1:2005 (Third Edition) + CORR. 1:2006 + CORR. 2:2007 + A1:2012) (FDA Consensus Standards number 19-4)
- IEC 60601-1-6: 2010 + A1: 2013, Edition 3.1 - Medical electrical equipment – Part 1-6: General requirements for basic safety and essential performance – Collateral standard: Usability (FDA Consensus Standards number 5-89)
- IEC 60601-1-3:2008 (Second Edition) + A1:2013 Medical electrical equipment - Part 1-3: General requirements for basic safety and essential performance - Collateral Standard: Radiation protection in diagnostic X-ray equipment (FDA Consensus Standards number 12-269)
- IEC 60601-2-54:2009, AMD1:2015 Medical electrical equipment - Part 2-54: Particular requirements for the basic safety and essential performance of X-ray equipment for radiography and radioscopy (FDA Consensus Standards number 12-317)
- IEC 62366: 2007 + A1: 2014, Edition 1.0 - Medical devices – Application of usability engineering to medical devices (FDA Consensus Standards number 5-114)
- ISO 14971:2019 Medical devices - Applications of risk management to medical devices (FDA Consensus Standards number 5-125)

Conclusion from clinical and nonclinical tests:

All detectors listed in Table 1 underwent non-clinical integration testing with the DRX-Evolution Plus system. These tests included functional testing, installation testing, media verification tests, performance tests, regression tests, risk mitigation testing, and serviceability testing. The Lux 35 Detector testing included comprehensive image quality tests, vacuum testing to validate its liquid ingress (IP57) requirement, and Dual Energy functionality and performance testing to verify that the Lux 35 Detector performed as expected.

Non-clinical safety and performance test results for the “Smart” Feature user options, developed to enhance workflow and exam set-up, indicated that the subject device as described in this submission meets the predetermined safety and effectiveness criteria.