January 20, 2023

Carestream Health, Inc.
℅ Jessica Deryke
Regulatory Affairs Manager
Building 7, No. 1510 Chuanqiao Road
China (Shanghai) Pilot Free Trade Zone
Shanghai, 201206
CHINA

Re: K223842
Trade/Device Name: DRX-Compass
Regulation Number: 21 CFR 892.1680
Regulation Name: Stationary x-ray system
Regulatory Class: Class II
Product Code: KPR
Dated: December 14, 2022
Received: December 22, 2022

Dear Jessica Deryke:

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,

Lu Jiang
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Lu Jiang, Ph.D.
Assistant Director
Diagnostic X-Ray Systems Team
DHT8B: Division of 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)*
K223842

Device Name
DRX-Compass

Indications for Use *(Describe)*
The device is indicated for use in obtaining diagnostic quality radiographic images to aid the physician with diagnosis. The system can be used to perform radiographic imaging of various portions of the human body, including the skull, spinal column, extremities, chest, abdomen and other body parts. The device is not indicated for use in mammography

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.***

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# "510(k) Summary"

K223842


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

**510(k) Owner Phone:** 585-627-6505
**510(k) Owner Fax:** 585-627-8802

**Contact Person & Info:** Jessica DeRyke
Regulatory Affairs Manager
Jessica.deryke@carestream.com
585-489-7627


**Date Summary Prepared:** December 9, 2022

**Predicate**
**510(k) Submitter:** Carestream Health, Inc.
**510(k) Number:** K201373
**Trade Name:** DRX-Compass
**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

**Modified**
**510(k) Submitter:** Carestream Health, Inc.
**Trade Name:** DRX-Compass
**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

**Device Description:**

The DRX-Compass System 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).

The DRX-Compass can be used with digital radiography (DR) and computed radiography (CR) receptors.

Smart Features are added to the DRX-Compass system to provide remote capabilities for existing functions of the DRX-Compass 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. These improvements are referred to as “smart features” in the product documentation. Implementation of these “smart features” does not change the intended use of the system.

- **Real-time Video Assistance:**

  The modified DRX-Compass System 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 modified DRX-Compass System provides the capability for the operator to select LLI parameters on the user interface without needing to physically be in the exam room. An LLI exam consists of two to five images stitched together to create one larger image of a leg or spine which is too long to show in a single image capture. The operator selects the top and bottom of the desired region of interest, and the system determines the number of images needed for the exam.

- **Collimation:**

  The modified DRX-Compass System allows the operator to collimate the intended location of the x-ray beam remotely from the user interface. Previously, the operator would have to physically go into the exam room and manually use collimator knobs to adjust the location of the light that represents the x-ray beam for purposes of exam set up.

- **Patient Picture:**

  The modified DRX-Compass System can now use camera to take a picture of patient to be delivered with the x-ray image. The patient picture interface supports the capture of a picture of the patient’s physical anatomy from the live camera view automatically while system is taking the exposure. The operator can add these pictures to the patient record, making the pictures available for viewing along with the acquired x-ray images.

**Indication for Use / Intended Use:**

The device is indicated for use in obtaining diagnostic quality radiographic images to aid the physician with diagnosis. The system can be used to perform radiographic imaging of various portions of the human body, including the skull, spinal column, extremities, chest, abdomen, and other body parts. The device is not indicated for use in mammography.

**Substantial Equivalence:**

Based upon information provided within this submission, we believe that the modified DRX-Compass, is substantially equivalent to the legally marketed DRX-Compass System (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-Compass System, has been found substantially equivalent by FDA through the 510(k) process and is legally marketed. The Indications for Use for the modified device are identical to the predicate indications for use.

According to 14971, Risk Management methodology, no new risks have been identified that raise additional questions of safety and performance. All product risks have been mitigated as far as possible and there have been no changes to risk control measures in the current product risk analysis. Testing to recognized FDA consensus standards and internal bench testing have indicated substantial equivalence.

**Comparison of Technological Characteristics**

A comparison chart (Figure 1) provides the similarities and differences between the modified and predicate devices.

**Figure 1: Comparison Chart**

| **Feature** | **Predicate DRX-Compass System (K201373)** | **Modified DRX-Compass System** |
|---|---|---|
| Digital Radiography Imaging Devices (Detector) | Carestream DRX Plus Detectors (K150766)<br>Focus 35C Detector (K192512)<br>Focus 43C Detector (K200622) | Supports the same detectors as the predicate devices and the additional detectors listed below:<br><br>DRX Plus 2530 (K183245)<br>Focus HD 35 (K213646)<br>Focus HD 43 (K213529)<br>Lux 35 (K203159) |
| Application System Software | Image View Software | Same |
| Wall Stand | Non-Tilting: WS-NT<br>Tilting options: WS-T | Same |
| Radiographic Table | Floating Top, non-Elevating QT-740<br>Floating Top, Elevating: QT-750 | Same |
| X-Ray Generator Options | Three Phase, CGF-50-2, CGF-50-3, CGF-65-3, and CGF-80-3 | Same |
| X-Ray Tube | Toshiba (Canon):E7254FX, E7252X | Same |
| X-Ray Collimator | Manual: Ralco R221/A DHHS<br>Automated: Ralco R221. ACS DHHS | Same |
| Electrical Safety | IEC 60601-1<br>IEC 60601-1-2<br>IEC 60601-2-54 | Same |

**Summary of Non-Clinical Performance 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 modified device demonstrates that the modified 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.

The flat panel detector DQE/MTF data shows that the additional detectors supported by the modified device (DRX-Compass) are equivalent in image quality to that of the DRX Plus detectors cleared with the predicate.

DRX-Compass 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)