Carestream Health, Inc.
% Duane Gutowski
Sr. Manager Regulatory Affairs, Clearance & Surveillance
Building 7, No. 1510 Chuanqiao Road
Pilot Free Trade Zone
Shanghai, Shanghai 201206
CHINA

June 26, 2020

Re: K201373
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: June 19, 2020
Received: June 22, 2020

Dear Duane Gutowski:

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)*
K201373

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.

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Carestream

"510(k) Summary"

K201373

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: Carolyn L Wagner
Director Regulatory Affairs, Clearance & Surveillance
carolyn.wagner@carestream.com
585-627-6588

Date Summary Prepared: May 22, 2020

Subject Device:

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

Predicate Device:

510(k) Submitter: Carestream Health, Inc.
Trade Name: Q-Rad System
510(k) Number: K193574
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, a ceiling mounted tube support, x-ray tube, and collimator (beam-limiting device).

The DRX-Compass can be used with digital radiography (DR) and computed radiography (CR) receptors. Systems equipped with DR or CR receptors can also be configured to include a workstation computer that is fully integrated with the x-ray generator.

The modified (subject) device, DRX-Compass, is the previously cleared Q-Rad System stationary x-ray system which has been modified as follows:

- New marketing names DRX-Compass and DR-Fit will be used depending upon regional marketing strategies.
- Implementation of a new wall stand that provides options for automated vertical motion and vertical to horizontal manual tilt (90 degrees).
- Implementation of a different Overhead Tube Crane (OTC): This OTC is ceiling suspended and provides x-y movement capability for the tube head with respect to the detector. The tube head is capable of three options for alignment with the image acquisition device (detector) as follows: 1) manual alignment by moving the x-ray tube support, 2) manual alignment using the "tube-up/tube-down" switch on the tube support, or 3) automatic alignment using the "Auto Position" switch to activate motors on the tube support in x, y, z, and alpha directions
- Focus 35C and Focus 43C Detectors are added as additional optional detector selections for customers ordering a DRX-Compass system.
- X-Ray Generator: Several Carestream designed generators are available with the system depending on power requirements and regional configurations. These generators are functionally identical to the generators currently offered for sale with the Q-Rad System.

Indications for Use / Intended Use:

The Indications for Use Statement for the DRX-Compass / DR-FIT as described in its labeling is:

"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."

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 Indications for Use for the subject device is the identical to that of the predicate device and the intended use remains unchanged.

Substantial Equivalence:

Based upon information provided within this submission, we believe that the modified Q-Rad System, DRX-Compass, is substantially equivalent to the legally marketed Q-Rad 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, Q-Rad System, has been found substantially equivalent by FDA through the 510(k) process (K193574) and is legally marketed. The Indications for Use for the subject device are identical to the predicate indications and can therefore be considered for substantial equivalence.

Risk assessment of the modifications to the Q-Rad System (DRX-Compass) described in this submission has not identified any new unmitigated risks for the system. Testing to recognized prevailing consensus standards and bench testing have indicated equivalent safety and performance of the modified device. We believe that the modifications to the Q-Rad System (DRX-Compass) do not raise new issues of safety and effectiveness and therefore support a substantial equivalence determination.

Discussion of Testing

The performance characteristics and operation / usability of the modified Q-Rad System (DRX-Compass) were evaluated in non-clinical (bench) testing. These studies have demonstrated the intended workflow, related performance, overall function, verification and validation of requirements for intended use, and reliability of the system software requirements. Non-clinical test results have demonstrated that the device conforms to its specifications. 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.