Carestream Health, Inc.
c/o Carolyn Wagner
Director Regulatory Affairs, Clearance and Surveillance
150 Verona Street
ROCHESTER, NY 14608

November 4, 2019

Re: K190330
Trade/Device Name: DRX-Evolution/Plus with Dual Energy
Regulation Number: 21 CFR 892.1680
Regulation Name: Stationary X-Ray System
Regulatory Class: Class II
Product Code: KPR
Dated: February 12, 2019
Received: February 14, 2019

Dear Carolyn Wagner:

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)*
K190330

Device Name
DRX-Evolution/Plus with Dual Energy

Indications for Use *(Describe)*
The device is a permanently installed diagnostic x-ray system for general radiographic x-ray imaging including tomography. This device also supports dual energy chest imaging. The tomography and dual energy features are 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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"510(k) Summary"

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 Wagner Director Regulatory Affairs carolyn.wagner@carestream.com 585-627-6588
Date Summary Prepared:	November 1, 2019
Device Trade Name:	DRX-Evolution/Plus with Dual Energy
Device Common Name:	System, X-Ray, Stationary
Classification Name:	Stationary x-ray system
Device Class:	II
Device Code:	KPR
Regulation Number:	21 CFR 892.1680
Primary Predicate Device:	Carestream DRX-Evolution/Plus
Device Common Name:	System, X-Ray, Stationary
Classification Name:	Stationary x-ray system
Device Class:	II
Device Code:	KPR
Regulation Number:	21 CFR 892.1680 Manufactured by: Carestream Health, Inc. 510(k) No.: K163203 (12/13/2016)
Secondary Predicate Device:	Dual Energy and Tissue Equalization Software Option
Device Common Name:	System, X-Ray, Stationarey
Classification Name:	Stationary X-ray System
Device Class:	II
Device Code:	KPR
Regulation Number:	21 CFR 892.1680 Manufactured by: General Electric Medical Systems 510(k) No.: K013481 (11/02/2001)

Device Description:

The modified Carestream DRX-Evolution/Plus is a stationary x-ray system with expanded capability to be used for Dual Energy adult chest radiographs. The only hardware change to the system to incorporate the Dual Energy functionality is a change to the existing collimator filter wheel. The previously cleared x-ray system contains a collimator filter wheel with multiple filters. For the Dual Energy Feature, a 0.5mm silver (Ag) filter was added to the 1mm aluminum (Al) filter location. This modified collimator filter wheel can be used for both general radiography and Dual Energy examinations.

The Dual Energy Feature is an imaging technique that takes advantage of the differential, energy-dependent absorption properties of bone and soft tissue structures in human anatomy. The operation consist of capturing two radiographic images of a patient in rapid succession, one at a relatively lower energy X-ray exposure compared to the second at a relatively higher energy exposure. These images are then subject to a weighted subtraction that can remove structures and produce three processed images, a Standard-of-Care image, a bone image, and a soft tissue image.

The Dual Energy Feature software includes a motion compensation option to suppress artifact due to involuntary patient motion that can occur between image acquisitions.

The DRX-Evolution/Plus system was cleared for use with tomography in a previous submission.

Indications for Use / Intended Use:

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

"The device is a permanently installed diagnostic x-ray system for general radiographic x-ray imaging including tomography. This device also supports dual energy chest imaging. The tomography and dual energy features are not to be used for imaging pediatric patients."

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 similar as that 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.

Substantial Equivalence:

Based upon information provided within this submission, we believe that the Dual Energy Feature is substantially equivalent to the legally marketed DRX-Evolution/Plus with ImageView software (primary predicate device) and to the Dual Energy and Tissue Equalization Software Options (secondary predicate device).

The DRX-Evolution/Plus with ImageView software (primary predicate device) operates the same as the modified DRX-Evolution/Plus with Dual Energy (subject device) except for the specific software and hardware modifications that enable dual energy adult chest examinations. These modifications consist of the addition of a 0.5mm silver (Ag) filter to the 1mm aluminum (Al) filter location and the dual energy software.

The Dual Energy and Tissue Equalization Software Options (secondary predicate) and the DRX-Evolution/Plus with Dual Energy (subject device) both capture a high and a low energy exposure of a patient in rapid succession. Both devices produce a bone image, a soft tissue image, and a composite image and have motion correction algorithms to compensate for subtle body movements. Both devices send three images to the operator's desired destination for diagnosis at the completion of the exam. These include a Standard-of-Care image, a bone image and a soft tissue image. The secondary predicate uses a fixed filtration for the high and low energy exposures while the subject device uses two different filtrations for the two exposures.

Refer to **Table 1** below for a summary of the similarities and differences between the subject device and both the primary and secondary predicates.

	Primary Predicate: Carestream DRX-Evolution	**Secondary Predicate: Dual Energy and Tissue Equilization Software Options for Digital Radiographic Systems**	**Subject Device: DRX-Evolution with Dual Energy Feature for Digital Radiographic Systems**
510(k) No.	K163203	K013481	K190330
Indications for Use	The device is a permanently installed diagnostic x-ray system for general radiographic x-ray imaging including tomography. The tomography feature is not to be used for imaging pediatric patients.	Dual Energy and Tissue Equalization software options are intended for use in generating digital radiographic images of human anatomy. This device is not intended for mammographic applications.	The device is a permanently installed diagnostic x-ray system for general radiographic x-ray imaging including tomography and dual energy. The tomography and dual energy features are not to be used for imaging pediatric patients.
Number of x-ray exposures in a DE exam	N/A	Two	Two
X-ray beam energies	N/A	60 kVp and 120 kVp	70 kVp and 120 kVp
Additional x-ray beam filtration	N/A	Fixed filtration: same filter for both exposures.	Differential filtration: 0.1 mm Cu at 70 kVp, and 0.5 mm Ag at 120 kVp
Time interval between exposures	N/A	200 ms	250 ms
Detector Matrix	DRX1 Plus GOS, CsI 3543 (2560 x 3072 x 16 bit) DRX1 Plus GOS, CsI 4343 (3072 x 3072 x 16 bit) 0.139 mm pixel pitch	FDR D-EVO Advanced C43A (2816 x 2817 x 16 bit) 0.150 mm pixel pitch	DRX1 Plus CsI 3543 (2560 x 3072 x 16 bit) DRX1 Plus CsI 4343 (3072 x 3072 x 16 bit) 0.139 mm pixel pitch
Detector scintillator material and imaging area	CsI, GOS 350 mm x 430 mm 430 mm x 430 mm	CsI 422 x 422 mm	CsI 350 mm x 430 mm 430 mm x 430 mm
Automatic Image Subtraction	N/A	Yes: one bone image with soft tissue information removed, and one soft tissue image with bone information removed	Yes: one bone image with soft tissue information removed, and one soft tissue image with bone information removed
Automatic involuntary patient motion reduction	N/A	Yes	Yes
Images sent to destination for diagnosis	N/A	Three images: standard of care (high kVp), soft tissue, and bone	Three images: standard of care (low kVp, high kVp, or composite), soft tissue, and bone

Table 1

Discussion of Testing

The performance characteristics and operation / usability of the Dual Energy Feature 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.

A chest phantom was used in dual energy imaging tests for the demonstration of the overall image quality and the radiation exposure. This phantom is anthropomorphic both in appearance, size, and x-ray attenuation characteristics. As the phantom only mimics a medium-to-small sized adult patient, we simulated larger sized patients by adding additional PMMA plates, each of 2.5 cm in thickness, to the phantom.

Posterial-anterial projection views were taken on the wall bucky at 180 cm SID, and anterial-posterial projection views were taken from the table bucky at 110 cm SID, which is the same as how the patient images are taken during normal clinical practices. Antiscatter grids and automatic exposure control were used, as these are required for dual energy imaging. Test results demonstrated that the phantom imaging exposure levels represent the routine imaging conditions intended for clinical use.

A clinical reader study was completed to evaluate the imaging performance of the Dual Energy software. The purpose of the study was to demonstrate the diagnostic image quality of the Dual Energy software with and without patient motion artifact reduction. A total number of one-hundred and twenty (120) Dual Energy studies were evaluated by three (3) board certified radiologists using a graduated 4 point RadLex rating scale based on diagnostic image quality (with a rating of 1 being non-diagnostic to a rating of 4 being exemplary). Results of the study were that the Dual Energy Feature delivers quality imaging performance that is rated diagnostic (3) or better when processed with or without patient motion artifact reduction.

Clinical data was provided in this submission to demonstrate that the low KV and high KV images are of comparable image quality to a standard/conventional PA chest radiograph.

Conclusion

Bench testing and clinical study results have demonstrated that the DRX-Evolution/Plus system with Dual Energy software feature is safe and effective. The information contained within this submission demonstrates that the device is as safe and effective as the primary and secondary predicate devices, and therefore supports a claim of substantial equivalence.

A Failure Modes Effects Analysis (FMEA) was performed to identify and assess potential risks to patients and/or users associated with the Dual Energy feature/functionality. This analysis included an assessment of controls currently included in the design of the product as well as identification of activities to be completed in order to: 1) gather additional information to ensure design robustness with respect to implementation of Dual Energy, 2) develop additional design features as needed to mitigate new risks, and 3) identify additional training to be conducted for operators.

The DRX-Evolution/Plus system conforms to the following safety standards:

IEC 60601-1
IEC 60601-1-2

IEC 60601-1-3
IEC 60601-1-6
IEC 62366
IEC 60601-2-54

In addition, the device conforms to applicable federal performance standards under 21 CFR 1020.

Carestream products (including the DRX-Evolution/Plus) are developed and tested to ensure quality in conformance with the FDA guidance document “Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices”.