Carestream Health, Inc.
c/o Duane Gutowski
Manager Regulatory Affairs, Clearance and Surveillance
150 Verona Street
ROCHESTER, NY 14608

December 20, 2019

Re: K191879
Trade/Device Name: DRX-Evolution with Carestream Digital Tomosynthesis
Regulation Number: 21 CFR 892.1680
Regulation Name: Stationary X-Ray System
Regulatory Class: Class II
Product Code: KPR, IZF
Dated: November 26, 2019
Received: November 29, 2019

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)*
K191879

Device Name
DRX-Evolution Plus with Carestream Digital Tomosynthesis

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 digital tomosynthesis. The tomography and digital tomosynthesis 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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Carestream

"510(k) Summary"

510(k) Owner Name:	Carestream Health, Inc.
510(k) Owner Address:	150 Verona Street Rochester, NY, 14608
510(k) Owner Phone:	585-627-8760
510(k) Owner Fax:	585-627-8802
Contact Person & Info:	Duane Gutowski Regulatory Affairs Manager dusty.gutowski@carestream.com 585-627-8760
Date Summary Prepared:	December 16, 2019
Device Trade Name:	DRX-Evolution with Carestream
Device Common Name:	Digital Tomosynthesis,
Classification Name:	Stationary x-ray system
Primary Device Class:	2
Primary Device Code:	KPR
Primary Regulation Number:	21 CFR 892.1680
Secondary Product Code	IZF
Predicate Device:	DRX-Evolution with Linear Tomography Manufactured by: Carestream Health, Inc. Systems 510(k) No.: K141837 (3/11/2015) 21 CFR 892.1680; KPR
Reference Device: **Reference 510(k) Submitter:**	FUJIFILM Medical Systems U.S.A., Inc., 419 West Avenue, Stamford, Connecticut, 06902 USA.

Reference Trade Name:	FUJFILM Tomosynthesis option for FDR AcSelerate Stationary X-ray System
Reference 510(k) Number:	K121499
Reference Regulation Description:	Tomographic x-ray system
Reference Review Panel:	Radiology
Reference Product Code:	IZF
Reference Regulation Number:	21 CFR 892.1740
Reference Device Class:	2

Reference Predicate Device Indications for Use – Fujifilm's Tomosynthesis option is intended to acquire images of human anatomy and to be used with Fujifilm's DR X-ray systems. Tomosynthesis is used to synthesize tomographic slices from a single tomographic sweep. It is not intended for mammographic applications.

Reference Predicate Device Description – Tomosynthesis is an advanced radiographic application that produces individual coronal "slice" images through an anatomical region of interest (ROI). To produce these slices multiple projection radiographic images are acquired in rapid succession as the X-ray tube sweeps and rotates across the ROI. Once acquired these projection images are subject to processing that registers and reconstructs them to individual tomographic slices.

We have included the Fuji FDR AcSelerate Stationary X-ray System with tomosynthesis, FDA 510k number K121499, as the reference predicate to support the differences in characteristic effects on the safety and effectiveness of the subject device.

Device Description:

Carestream Digital Tomosynthesis (DT) is a limited "sweep" imaging technique that generates multiple two-dimensional (2D) coronal slices (i.e. planes) from a series of low dose x-ray images of the same anatomy taken at the same exposure but at different angles. During a tomosynthesis acquisition the detector will be stationary while the tube head travels (sweeps) in a straight path (i.e. focal spot travel path). For each exposure, the tube will be angled toward the center of the detector.

The Carestream Digital Tomosynthesis contains 3 options: Sweep angle option is to provide the desired slice thickness. The number of images per degree of sweep angle. The Projection Image Resolution allows for the selection of speed of capture versus image resolution.

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 digital tomosynthesis. The tomography and digital tomosynthesis 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.

Comparison of Technological Characteristics:

Based upon information provided within this submission, we believe that the Carestream Digital Tomosynthesis is substantially equivalent to the legally marketed DRX-Evolution Plus with Linear Tomography, the identified predicate device.

Digital tomosynthesis operates based on the same principle as linear tomography except the detector can either be mechanically motorized in synchronization with the x-ray source or simply be stationary during the exam. The digital tomosynthesis implemented by Carestream chooses to use a stationary x-ray detector for the purpose of reducing motion blur and improving spatial resolution.

Both linear tomography and digital tomosynthesis use a sweep angle to isolate the anatomy of interest. By establishing the initial pivot level (fulcral plane) and exposing across the sweep angle the anatomical details in the fulcral plane are persevered, while anatomical clutter above or below the plane will be blurred. Both linear tomography and digital tomosynthesis isolate the anatomy of interest in the fulcral plane from unwanted clutter and improve the contrast to noise ratio of the image details.

Each linear tomography acquisition uses one single continuous x-ray exposure. Many acquisitions are frequently needed in order to fully cover the anatomical area of interest. This would increase the overall exam time and the total radiation dose by the total number of scans. As the overall exam time and the total radiation dose must be limited, the number of tomographic scans is limited.

Digital tomosynthesis uses multiple low-power, pulsed x-ray exposures instead of a single continuous exposure. Correspondingly the x-ray detector in a digital tomosynthesis exam will capture each short x-ray pulse as individual images from different projection angles of the x-ray source. These projections are used to reconstruct a stack of digital tomosynthesis

slices for viewing, which each slice equivalent to a traditional tomogram with the fulcral plane set at the center of the digital tomosynthesis slice.

As the image acquisition is separated from the digital tomosynthesis image volume formation process, a reconstruction process is used to maximize the anatomy contrast to noise ratio in the tomosynthesis slices. The Carestream Digital Tomosynthesis reconstruction software leverages algorithms that are the same in principle to those applied in the computed tomography (CT), such as filtered back projection or iterative reconstruction etc. As a result the anatomical details are greatly improved with digital tomosynthesis when compared to traditional linear tomography.

Discussion of Testing

The performance characteristics and operation / usability of the Carestream Digital Tomosynthesis 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 clinical reader study was completed to evaluate the imaging performance of the Carestream Digital Tomosynthesis software. The purpose of the study was to demonstrate the diagnostic image quality of the Carestream Digital Tomosynthesis feature. This image quality evaluation was done against a reference comparison which was the standard of care PA and lateral chest x-rays. Additionally, phantom Digital Tomography studies were done including a scout and Digital Tomosynthesis volume from the investigational device and a Linear Tomography exam to serve as the predicate device comparison.

Seventeen (17) Digital Tomosynthesis image cases were acquired from adult human subjects (patients) from a clinical study conducted at Toronto General Hospital located in Toronto, Ontario, Canada. Each Digital Tomosynthesis (DT) case consisted of each study participant having a thoracic digital radiograph (DR) exam (an exam includes a PA and lateral chest exposure) and a DT exam (a scout PA chest image and the DT exposures).

In addition, 11 Digital Tomosynthesis phantom exams and corresponding Linear Tomography exams were captured. The acquired clinical exams met the inclusion/exclusion criteria. X-ray images were acquired using appropriate device dependent exposure for Digital Tomosynthesis acquisitions.

Seven (7) board certified radiologists, of general varying reading experience performed an evaluation of the images/exams captured using investigational, reference and predicate devices.

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) was used to determine the quality of the scout and digital tomosynthesis exams. The mean RadLex rating for the scout and Digital Tomosynthesis is 3.7156 with none of the ratings being non-diagnostic.

The statistical test results demonstrate the Carestream Digital Tomosynthesis delivers quality imaging performance that is equivalent or better in diagnostic quality compared to images obtained using commercially available predicate and reference devices.