May 17, 2019

Carestream Health, Inc.
% Gina Maiolo
Regulatory Affairs Manager
150 Verona Street
ROCHESTER NY 14608

Re: K191025
Trade/Device Name: DRX-Revolution Mobile X-ray System
Regulation Number: 21 CFR 892.1720
Regulation Name: Mobile x-ray system
Regulatory Class: Class II
Product Code: IZL
Dated: April 18, 2019
Received: April 19, 2019

Dear Gina Maiolo:

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 and Part 809); 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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

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)*
K191025

Device Name
DRX-Revolution Mobile X-ray System

Indications for Use *(Describe)*
The device is designed to perform radiographic x-ray examinations on all pediatric and adult patients, in all patient treatment areas.

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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K191025

510(k) Summary

510(k) Owner:
Carestream Health, Inc
150 Verona Street
Rochester, New York 14608
Contact: Gina Maiolo
Regulatory Affairs Manager
585.627.6543
585.454.1894

Carestream Health, Inc. is submitting this Special 510(k) premarket notification for modifications to the DRX-Revolution Mobile X- ray System. Caresteam believes this modified device is substantially equivalent to the cleared device (K120062).

Date Summary Prepared: April 15 2019		
	Predicate	**Subject**
Device Trade Name	DRX-Revolution Mobile X-ray System	DRX-Revolution Mobile X-ray System
Device Common Name	Mobile X-ray System	Mobile X-ray System
Classification Name	Mobile X-ray System	Mobile X-ray System
Device Class	Class II	Class II
Device Code	IZL	IZL
Regulation Number	21 CFR 897.120	21 CFR 897.120
Predicate Device	DRX-Revolution Mobile X-ray System (K120062)	DRX-Revolution Mobile X-ray System (K191025)

Indications for Use

"The device is designed to perform radiographic x-ray examinations on all pediatric and adult patients, in all patient treatment areas."

In addition, the indications for use of the modified device, as described in labeling does not change as a result of the device modification(s).

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Device Description

The DRX-Revolution Mobile X-ray System is a diagnostic mobile x-ray system utilizing digital radiography (DR) technology. The system consists of a self-contained x-ray generator, image receptor(s), imaging display and software for acquiring medical diagnostic images outside of a standard stationary x-ray room. The DRX-Revolution system incorporates a flat-panel detector that can be used wirelessly for exams such as in-bed chest projections. The system can also be used to expose CR phosphor screens or films.

The DRX-Revolution Mobile X-ray System is designed for digital radiography (DR) with Carestream detectors. The system also offers:

- A high-power, 32 kW generator
- A maneuverable drive system
- X-ray tube positioning in five axes of motion
- A telescoping column for better visibility while driving
- Storage for detectors and supplies
- A touchscreen user interface

Technological Characteristics

The modified DRX-Revolution Mobile X-ray System is substantially equivalent to the predicate device currently cleared on the market (K120062). The modified DRX-Revolution employs the same fundamental scientific technology as the predicate device. Both systems consist of an x-ray generator, x-ray tube, collimator, and graphical user interface (GUI) that runs image acquisition software that is displayed on primary/secondary monitors. These components are mounted on a motorized cart that is battery powered to enable the device to be driven from location to location by user interaction. Both systems utilize a digital flat panel detector for image capture. The following summarize the modifications to the DRX-Revolution System:

- The majority of the modifications to the DRX-Revolution X-ray System are specific to the tube head assembly. Both the predicate and modified device are designed with this same tube head assembly technology, however, the modified device uses an X-ray tube by a different supplier utilizing the same technical specifications as the X-ray tube in the predicate. There are minimal differences, such as size and weight of the replacement tube resulting in less weight of the entire tube head assembly. The change in X-ray tube does not significantly change the functionality of the redesigned DRX-Revolution system, nor do changes significantly affect the safety or effectiveness of the device. Tube head assembly modifications and other modifications are fully documented in the Substantial Equivalence section of this submission.

- The modified DRX-Revolution system is designed to be used with the legally marketed Carestream detectors: Carestream DRX-1 (K090318), DRX-1C (K120062), and will include additional support for the DRX Plus detectors, these detectors that have been previously cleared for use under the following 510(k) submissions:
  - Carestream DRX Plus 3543 and 3543C Detectors (K150766)
  - Carestream DRX Plus 4343 and 4343C Detectors (K153142)
  - Carestream DRX Plus 2530 and 2530C Detectors (K183245)

- Image acquisition software that drives the mobile system has been replaced with ImageView (IV) platform software. This is a web-based software application which improves the usability of the system for end users and changes the look and feel of the user interface (GUI). No changes have been made between the DRX Carestream Evolution with ImageView (K163203) and the subject device with ImageView, other than some minor changes necessary for the software to function on the subject device. The image processing between the two devices is the same. This change has no clinical impact on image diagnosis, bench testing data demonstrates substantial equivalence. Additionally, ImageView Software has been previously cleared for use under a 510(k) submission with the Carestream DRX-Evolution stationary X-ray System with Carestream DRX-1 and DRX-1C Detectors (K163203).

  Not replacing any previous detectors that were cleared with the predicate, we are introducing additional detectors that have clearance on the market and are listed in the Comparison table for the subject device.

- The High-voltage X-ray generator has been replaced. This generator is considered a 1:1 replacement, there was no change in performance specifications. The generator was verified and validated and passed all testing and demonstrates there is no significant impact on clinical functionality or performance that could significantly affect safety and effectiveness.

- Improvements to quiet the system were implemented on the modified device. Specific changes impacted the drive motors and the brakes, allowing for less vibration than the predicate.

- Changes to improve motion control by the modification of firmware. The cart firmware has the ability to monitor and detect status of specific circuits which will result in more control over cart movement and preventing unintended motion occurrences.

Risks were assessed in accordance to ISO 14971 and risk control options were implemented with safety by design principles and with a risk methodology that reduces risks as far as possible.

Summary of Non-Clinical Testing

Clinical testing was not required to establish substantial equivalence. Bench testing was sufficient to assess the device safety and effectiveness. The performance of the redesigned DRX-Revolution was evaluated in non-clinical (bench) testing using a Phantom Imaging study. A technical analysis (non-diagnostic) of image quality attributes such as detail, sharpness, noise and appearance of artifacts were compared for each image. Results of this data demonstrated that image quality on the modified DRX-Revolution Mobile X-ray System is equivalent to the device on the market. In summary, appropriate bench testing was performed with the modified device and the 510(k) cleared detectors being introduced. Testing demonstrates that the modified device produces diagnostic image quality that is the same or better than the predicate. The detectors have been tested and verified to meet the requirements for integration with the DRX-Revolution Mobile X-ray System (modified) device and the DQE/MTF data demonstrates image quality is the same as or better than the predicate.

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Summary of Guidance & Standards Compliance

Carestream has reviewed the following FDA Guidance and will meet the guidance recommendations as they apply to the DRX Revolution Mobile X-ray System.

- Content of Premarket Submissions for Management of Cybersecurity in Medical Devices Guidance for Industry and Food and Drug Administration Staff Document Issued on: October 2, 2014

- Pediatric Information for X-ray Imaging Device Premarket Notifications Guidance for Industry and Food and Drug Administration Staff Document issued on November 28, 2017

- Guidance for the Submission of 510(k)s for Solid State X-ray Imaging Devices Guidance for Industry and Food and Drug Administration Staff Document issued on: September 1, 2016

- Guidance for Industry and FDA Staff Guidance for the Content of Premarket Submissions for Software contained in Medical Devices, Document issued on: May 11, 2005 Medical Devices, Document issued on: May 11, 2005

- Guidance for Industry and FDA Radio Frequency Wireless Technology in Medical devices Guidance for Industry and Food and Drug Administration Staff Document issued on: August 14, 2013 Document issued on: August 14, 2013

Applicable standards:

- ISO 14971:2007 Medical Devices: Application of risk management to medical devices
- IEC 60601-1-6: 2010 + A1: 2013, Edition 3.0 - Medical electrical equipment – Part 1-6: General requirements for basic safety and essential performance – Collateral standard: Usability
- 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)
- IEC 60601-1-2:2014 Electro-Magnetic Compatibility including FCC Part 15 Subpart B:2018
- IEC 60601-1-3:2008 (Second Edition) + A1:2013 Medical electrical equipment - Part 1-3: General Requirements for Radiation Protection in Diagnostic X-Ray Equipment
- IEC 60601-2-28:2017 Part 2: Particular requirements for the safety of X-ray source assemblies and X-ray tube assemblies for medical diagnosis
- IEC 60601-2-54:2009, AMD1:2015 Medical electrical equipment - Part 2: Particular requirements for the basic safety and essential performance of X-ray equipment for radiography and radioscopy
- IEC 62304:2006 (First Edition) + A1:2015 Medical device software Software life-cycle processes
- IEC 62366: 2007 + A1: 2014, Edition 1.0 - Medical devices – Application of usability engineering to medical devices
- Digital Imaging and Communication in Medicine (DICOM)

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A comparison chart provides similarities and differences between the modified and predicate device.

	DRX Mobile X-ray System (K120062)	**DRX Mobile X-ray System (K191025)**
Indications for Use	The device is designed to perform radiographic x-ray examinations on all pediatric and adult patients, in all treatment areas.	*Same
Imaging Device Compatibility	Film, Computed Radiography (CR) Digital Radiography (DR)	*Same
Digital Radiography Imaging Device (Detector)	Carestream DRX-1 Detector (K090318) Carestream DRX-1C Detector (K120062)	*Same – additional support for the following: Carestream DRX Plus 3543 and 3543C Detectors (K150766) Carestream DRX Plus 4343 and 4343C Detectors (K153142) Carestream DRX Plus 2530 and 2530C Detectors (K183245)
X-ray Generator Rating	32kW	*Same
X-ray Tube Voltage Range	40-150kV(1kV steps)	*Same
X-ray Tube Manufacture/Model	Varian/RAD 68	Toshiba/XRR-3336X
X-ray Tube Focal Spot Size	0.6 and 1.2	*Same
mAs Range	0.1-320 mAs	*Same
System Power for Charging	Single Phase AC: 50/60 Hz, 1440 VA Voltage:100-240V	*Same
Application System Software (Operator Console X-ray Control)	Carestream DirectView System software with image processing capability	*Same ImageView System software with image processing capability (K163203)
Grid Alignment Software	Yes	No
Collapsible Column	Yes	*Same
Column Height	1298 mm-1961 mm	2193mm-1390mm
Column Rotation Range	+/- 270 degrees	*Same
Travel Method	Electric motor (battery powered)	*Same

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Conclusion

- The image quality of the modified device is at least as good as or better than that of the predicate device.
- Results of non-clinical testing demonstrate that the modified device is as safe and as effective as the predicate device.
- The intended use remains unchanged.
- The fundamental scientific technology of the modified device is the same and is substantially equivalent to the predicate.

The comparison chart demonstrates overall that the characteristics are primarily the same. For the identified differences from predicate to subject do not constitute a new intended use and the minor differences in the technological characteristics do not affect or raise new queries of safety and effectiveness based on risk analysis and conformance to recognized performance standards as listed above. The subject device is expected to be safe and effective for the device indications and are substantially equivalent to the predicate.