March 23, 2022

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

Re: K213568
Trade/Device Name: DRX-Rise Mobile X-ray System
Regulation Number: 21 CFR 892.1720
Regulation Name: Mobile x-ray system
Regulatory Class: Class II
Product Code: IZL
Dated: January 31, 2022
Received: February 7, 2022

Dear Ms. 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); 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,

Laurel Burk, Ph.D.
Assistant Director
Diagnostic X-ray Systems Team
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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K213568

Device Name
DRX-Rise 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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510(k) Summary

DRX-Rise Mobile X-ray System (K213568)

Date Prepared: January 31, 2022

1. General Information

Carestream Health, Inc
150 Verona Street
Rochester, New York 14608
Contact:

2. Contact Person

Gina Maiolo
Regulatory Affairs Manager
585.627.6543 (Work)
516.395.0597 (Mobile)

3. Device Name and Classification

Trade Name: DRX-Rise Mobile X-ray System
Classification Name: Mobile X-ray System
Classification Panel: Radiology
Classification Regulation: 21 CFR 892.1720 Device
Classification: Class II
Primary Product Code: IZL

4. Legally Marketed Predicate Device

Trade Name: DRX-Revolution Mobile X-ray System
Classification Name: Mobile X-ray System
Classification Panel: Radiology
Classification Regulation: 21 CFR 892.1720 Device
Classification: Class II
Primary Product Code: IZL
K191025

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5. Device Description

The DRX-Rise Mobile X-ray System is a diagnostic mobile X-ray system utilizing digital radiography technology. The DRX-Rise 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. 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.

The DRX-Rise system incorporates a flat-panel detector that can be used wirelessly for exams such as in-bed chest projections. The device acquires images using Carestream's clinical acquisition software platform (ImageView) and digital flat panel detectors. ImageView is considered software that is of Moderate Level of Concern and not intended for manipulation of medical images.
The DRX-Rise 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
- Storage for detectors and supplies
- A touchscreen user interface

6. Indications for Use

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

7. Substantial Equivalence

The DRX-Rise Mobile X-ray System is substantially equivalent to the predicate device currently cleared on the market (K191025).

- Both the predicate and the modified device (DRX-Rise) have the same principles of operation and share the same fundamental technology such as, an X-ray generator, X-ray tube, collimator, and graphical user interface (GUI) that displays image acquisition software to support image management.
- The indications for use are the same as the predicate
- The predicate device (DRX-Revolution Mobile X-ray System) uses a Canon tube (model XRR-3336X) while the modified device (DRX-Rise Mobile X-ray System) uses a Canon tube (model E7242-X/FX/GX). There are minimal differences between the models such as kV and focal spot size. The modified device is substantially equivalent to the predicate in terms of kV range. The tube model used in the modified device does not significantly

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change the functionality of the DRX-Rise system, nor impact safety and performance of the device or impact image quality.

- The modified device is designed with a fixed column versus the automatic collapsible column on the predicate device. The height of the modified column is 1930 mm whereas the height of the column on the predicate is 2193mm-1390 mm. The column rotation remains the same (+/- 270 degrees). This design change does not impact safety or performance.

- The modified device uses the same digital flat panel detectors that are designed to work across all Carestream Digital Radiography Systems. The detectors have either obtained clearance by separate submissions or with the digital radiography systems they are used with. The DRX-Rise is designed to be used with the legally marketed Carestream detectors:
    - DRX Plus 3543, DRX Plus 3543C (K150766) (cleared with predicate K191025)
    - DRX Plus 4343, DRX Plus 4343C (K153142) (cleared with predicate K191025)
    - DRX Plus 2530C (K183245) (cleared with predicate K191025)

- The image Acquisition Software on the modified device is the same as that of the legally marketed device (K191025). Carestream's ImageView Software has already obtained clearance on several Carestream digital radiography systems:
    - DRX-Revolution Mobile X-ray System (K191025)
    - DRX–Evolution System (K163203)
    - Q-RAD System (K193574)
    - OnSight 3D Extremity System (K160723)

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Table 1. Comparison of Technological Characteristics

	DRX-Revolution Mobile X-ray System (predicate device K191025)	DRX-Rise Mobile X-ray System (modified device K213568)	Impact
Indications for Use	The device is designed to perform radiographic X-ray examinations on all pediatric and adult patients, in all patient treatment areas.	*Same	
Imaging Device Compatibility	Digital Radiography (DR)	*Same	
Digital Radiography Imaging Device (Detector)	DRX Plus Detectors (K150766) (K153142) (K183245)	*Same	
X-ray Generator Rating	32kW	*Same	

mAs Range (Generator)	0.1-320 mAs	0.1 mAs～630 mAs	The DRX Rise (modified device) provides more power in generator output. No impact to safety/performance
X-ray Tube Voltage Range	40-150kV(1kV steps)	40-125kV (1kV steps)	40-125kV is the most commonly used kV range in clinical imaging. No impact to safety/performance
X-ray Tube Model	Canon/XRR-3336X	Canon/E7242 (X / FX / GX)	Same supplier but different tube model is used with the modified device. No impact to safety/performance
X-ray Tube Focal Spot Size	0.6mm and 1.2mm	0.6 mm and 1.5 mm	Small focal spot size is same as predicate. Large focus spot size is 20% larger but within expected range for clinical imaging. No impact to safety/performance or to image quality
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 ImageView System software with image processing capability (K191025)	*Same	
Collapsible Column	Yes	No	The column is fixed on the modified device. No impact to safety/performance
Column Height	2193mm-1390mm	1930mm (fixed column)	No impact to safety/performance
Column Rotation Range	+/- 270 degrees	*Same	
Travel Method	Electric motor (battery powered)	*Same	

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8. Summary of Non-clinical Data

No clinical data is necessary to evaluate the safety or performance for purposes of determining substantial equivalence of modifications to the DRX-Rise System. The non-clinical testing demonstrates that the modified device is substantially equivalent to that of the predicate device.

- Product verification and validation is sufficient to assess safety and performance of the modified device.
- Non-clinical testing (consensus standards testing and third-party product safety testing) of the modified device are sufficient to evaluate the safety and performance and demonstrate substantial equivalence.
- The DRX-Rise complies with the following FDA-recognized consensus 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 60601-1-2:2014 Medical electrical equipment -- Part 1-2: General requirements for basic safety and essential performance -- Collateral Standard: Electromagnetic disturbances -- Requirements and tests (FDA Consensus Standards number 19-8)

- 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)

- IEC 62304:2006 (First Edition) + A1:2015 Medical device software Software life-cycle processes (FDA Consensus Standards number 13-79)

- ISO 14971:2019 Medical devices - Applications of risk management to medical devices (FDA Consensus Standards number 5-125)

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9. Summary of Guidance

Carestream has reviewed the following FDA Guidance and will meet the guidance recommendations as they apply to the DRX-Rise 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: 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: August 14, 2013 Document issued: August 14, 2013

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10. Conclusion

The modified device (DRX-Rise Mobile X-ray System) is determined to be substantially equivalent to that of the legally marketed predicate device cleared under K191025.
The following are the basis for substantial equivalence:

- Same Indications for use as the predicate device.
- Same principles of operation and technological characteristics as the legally marketed predicate device.
- Same components, including same imaging chain process and software (Eclipse II K180809) as the predicate.
- Same image acquisition software (Carestream ImageView Software) is the same as that of the predicate and has been previously cleared on several Carestream digital radiography devices.
    - DRX-Revolution Mobile X-ray System (K191025)
    - DRX–Evolution System (K163203)
    - Q-RAD System (K193574)
    - OnSight 3D Extremity System (K160723)
- Same flat panel detectors will be supported by the modified device.
    - DRX Plus 3543, DRX Plus 3543C (K150766) (cleared with predicate K191025)
    - DRX Plus 4343, DRX Plus 4343C (K153142) (cleared with predicate K191025)
    - DRX Plus 2530C (K183245) (cleared with predicate K191025)