December 10, 2024

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

Re: K241505
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: November 12, 2024
Received: November 12, 2024

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

Lu Jiang

Lu Jiang, Ph.D.
Assistant Director
Diagnostic X-Ray Systems Team
DHT8B: Division of Radiologic Imaging
Devices and Electronic Products
OHT8: Office of 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: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K241505

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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510(k) Summary

K241505

510(k) Owner Name	Carestream Health, Inc.
510(k) Owner Address	150 Verona Street Rochester, New York 14608
510(k) Owner Contact Information	Gina Maiolo Regulatory Affairs Manager
Phone (Mobile)	516.395.0597
Date Summary Prepared	October 28 2024
Device Trade Name	DRX-Revolution Mobile X-Ray System
Device Common Name	Mobile System
Classification Name	Mobile X-ray system
Device Class	Class II
Device Code	IZL
Regulation Number	21 CFR 892.1720.
Predicate Device	DRX-Revolution Mobile X-Ray System (K191025)

Carestream Health, Inc. is submitting this Traditional 510(k) premarket notification for modifications to the DRX-Revolution System. Carestream believes that the modified device is substantially equivalent to the cleared device (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".

Device Description

The DRX-Revolution Mobile X-ray System is a mobile diagnostic x-ray system that utilizes digital technology for bedside or portable exams. Key components of the system are the x-ray generator, a tube head assembly (includes the x-ray tube and collimator) that allows for multiple axes of movement, a maneuverable drive system, touchscreen user interface(s) for user input. The system is designed with installable software for acquiring and processing medical diagnostic images outside of a standard stationary X-ray room. It is a mobile diagnostic system intended to generate and control X-rays for examination of various anatomical regions.

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Technological Characteristics

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

- The modified DRX-Revolution consists of the same fundamental scientific technology and is designed with the same operating principles as the predicate device. The predicate and modified device consist of the same critical components: an x-ray generator, x-ray tube, collimator, and image acquisition software (ImageView) to support image / patient management.
- The digital radiography application software has been cleared for use across the following Carestream digital radiography devices: DRX-Evolution System (K163203), DRX-Compass System (K223842), DRX-Revolution (K191025).
- The ImageView software is the same image acquisition software installed on the predicate device (K191025). Eclipse II, the image processing software (designed into ImageView) and the imaging processing components cleared on the predicate device are the same on the modified device. The predicate was cleared with ImageView V1.0 and the modified device will run ImageView V2.0. The difference in versions do not raise additional question on safety or performance. The below key functionality offered in V2.0 is the same on the cleared device.

  · Configuration of operational parameters
  · Patient creation
  · Patient worklist
  · Status Display (acquisition, delivery, errors, etc.)
  · X-Ray Generator operation
  · Image acquisition
  · Image review
  · Communication to external HIS, RIS, PACS, and printers

- The modified DRX-Revolution system is compatible with the following legally marketed Carestream detectors (same detectors cleared with the predicate device): DRX Plus 3543C (K150766), DRX Plus 4343C (K153142), DRX Plus 2530C (K183245).
- The Lux 35 detector is an additional detector that will be available for sale with the DRX-Revolution. Lux 35 was cleared (K203159) in a separate submission and is determined substantially equivalent to the DRX Plus detectors as the MTF/DQE data demonstrates.
- Smart Noise Cancellation (SNC) on the mobile x-ray system produces the same image output as the in-room x-ray system (with SNC). Comparison testing was performed and demonstrates imaging output and performance on the mobile system is the same as it is on the in-room system.

Comparison of Technological Characteristics

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

	Predicate Device	**Subject Device**	**Comments**
Device Name	**DRX-Revolution Mobile X-ray System**	**DRX-Revolution Mobile X-ray System**	
510(k) Number	K191025	K241505	
Device Classification Name	Mobile X-ray System	Mobile X-ray System	

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Intended Use	The device is designed to perform radiographic x-ray examinations on all pediatric and adult patients, in all patient treatment areas.	Same	No impact
X-ray Generator Model/Rating	Carestream Generator (32kW)	Same	No impact
X-ray Tube Manufacture/Model	Toshiba/XRR-3336X	Same	No impact
Image Processing Software	Eclipse II	Same	No impact
DR Application System Software	ImageView Software	Same	No impact
Smart Noise Cancellation (SNC)	No	Yes	SNC is cleared with a stationary x-ray system (DRX Evolution - K202441). SNC functions the same on the DRX-Revolution system (mobile) as it does on the DRX-Evolution (in-room) system. Comparison testing shows SNC image output is the same on the mobile system as it is on the cleared in-room system (K202441). Supplemental data demonstrates the testing for Smart Noise Cancellation (SNC) on the DRX-Revolution (mobile system) is comprehensive and the functionality was adequately tested.
Digital Flat Panel Detectors	DRX Plus 3543C, 4343C (K153142) DRX Plus 2530C (K183245)	Same Lux 35 Detector (K203159)	Lux 35 obtained clearance in a separate submission K203159. Addition of a detector has no impact on image quality or on the imaging system. Lux 35 is substantially equivalent to the DRX Plus detectors. System integration testing was performed to support integration of the compatible detectors with the DRX-Revolution system using ImageView Software v2.0.
Align Assist	No	Yes	Improvement to optimize workflow operation.
Inching	No	Yes	Additional option for movement of the cart.

			Verification and validation testing of both hardware and software were completed to demonstrate safety and performance.
Cumulative Changes	Yes	Yes	Design improvements to components (component-level functionality same on predicate) • Generator components • Tube head handles • Tube head covers • Cord Reel

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Summary of Non-Clinical Testing

Clinical testing was not required to establish substantial equivalence. Performance testing was sufficient to assess the device safety and effectiveness and to demonstrate that the modified device is substantially equivalent to the cleared device.

Comparison testing was performed to demonstrate SNC image output is the same on the mobile system as it is on the in-room system (K202441). A pixel-by-pixel analysis was used to determine whether the SNC processing performed on the DRX-Revolution Mobile X-ray system is considered equivalent to the SNC processing performed on the DRX-Evolution Plus system. The processed images on both systems were visually compared on a diagnostic monitor using flicker comparison (fast switching of registered images to detect small differences) and no perceptible differences were observed when compared at 200% magnification. The results of the SNC images demonstrated that at least 99% of all image pixels were within ± 1 pixel value. All pixels in the output image must be within +/-1 pixel value and the absolute maximum difference seen across all the test images was 3-pixel values, thus meeting the acceptance criteria of a maximum allowable difference of 10-pixel values.
Additionally, a noise ratio metric was created to compare the SNC noise field difference with the expected system noise variation. All noise ratio values computed for every pixel of the test images were less than 1.0 indicating that the difference in SNC noise fields between the Evolution and Revolution systems was less than the expected system noise, further supporting the conclusion that the SNC image differences on the mobile system are undetectable.

The following consensus standards were met:

- ISO 14971:2019 Application of risk management to medical devices
- ISO 20471:2021 Medical devices - Information to be supplied by the manufacturer
- IEC 62366-1:2015+A1:2020 Medical devices - Part 1: Application of usability engineering to medical devices
- ISO 15223-1:2021 Medical devices - Symbols to be used with information to be supplied by the manufacturer - Part 1: General requirements
- 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 60601-1-2:2015 Electro-Magnetic Compatibility including FCC Part 15 Subpart B:2018
- IEC 60601-1-3:2008+A2:2021 (Second Edition) + A1:2013 Medical electrical equipment - Part 1-3: General Requirements for Radiation Protection in Diagnostic X-Ray Equipment
- IEC 60601-1-6:2010 + A1:2015, Edition 3.0 Medical electrical equipment – Part 1-6: General requirements for basic safety and essential performance – Collateral standard
- IEC 60601-2-54:2009+A1:2015 Particular requirements for the basic safety and essential performance of X-ray equipment for radiography and radioscopy
- 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 62304:2006 + A1:2015 Medical device software Software life-cycle processes
- ISO 10993-1:2018 Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process
- Digital Imaging and Communication in Medicine (DICOM)