March 11, 2026

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

Re: K253185
Trade/Device Name: Lux HD Detecotrs, DRX-LC Detector, 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, MQB
Dated: September 17, 2025
Received: September 26, 2025

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 Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), and ISO 13485 clause 8.5 (Corrective and preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and 21 CFR 820.70) and document changes and approvals in the Medical Device File (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 Management System Regulation (QMSR) (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 Radiological 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.

510(k) Number *(if known)*
K253185

Device Name
Lux HD Detectors, DRX-LC Detector, DRX-Revolution Mobile X-ray System

Indications for Use *(Describe)*

DRX-Revolution Mobile X-ray System
The device is designed to perform radiographic x-ray examinations on all pediatric and adult patients, in all patient treatment areas.

Lux HD Detectors
Lux HD 35 Detector and Lux HD 43 Detector are indicated for digital imaging solutions designed to provide general radiographic diagnosis for human anatomy including both adult and pediatric patients. They are intended to replace film/screen systems in all general–purpose diagnostic procedures. Lux HD 35 Detector and Lux HD 43 Detector are not intended for mammography or dental applications.

DRX-LC Detector
DRX-LC, as a major imaging component, are supplied to the manufacturers of medical diagnostic X-ray photography systems and used in conjunction with the medical diagnostic X-ray photography system to image the object to be checked. They are capable of outputting the acquired static images to a processing device after acquisition.

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.

510(k) Summary

510(k) Owner Name	Carestream Health
510(k) Owner Address	150 Verona Street Rochester, New York 14608
510(k) Owner Contact Information Phone (Mobile)	Gina Maiolo 516 395 0597
Date Summary Prepared	March 9, 2025
Device Trade Name(s)	Lux HD Detectors, DRX-LC Detector, DRX-Revolution Mobile X-Ray System
Device Common Name(s)	Mobile X-ray System, Solid State X-ray Imager (Flat Panel/Digital Imager)
Classification Name(s)	Mobile X-ray System Detectors, Solid State X-ray Imager (Flat Panel/Digital Imager)
Device Class	Class II
Device Code(s)	IZL, MQB
Regulation Number(s)	892.1720 - Mobile X-ray system
Predicate Device(s)	Lux HD Detectors DRX-Revolution Mobile X-ray System

Indications for Use

DRX-Revolution Mobile X-ray System
The device is designed to perform radiographic x-ray examinations on all pediatric and adult patients, in all patient treatment areas.

Lux HD Detectors
Lux HD 35 Detector and Lux HD 43 Detector are indicated for digital imaging solutions designed to provide general radiographic diagnosis for human anatomy including both adult and pediatric patients. They are intended to replace film/screen systems in all general–purpose diagnostic procedures. Lux HD 35 Detector and Lux HD 43 Detector are not intended for mammography or dental applications.

DRX-LC Detector
DRX-LC, as a major imaging component, are supplied to the manufacturers of medical diagnostic X-ray photography systems and used in conjunction with the medical diagnostic X-ray photography system to image the object to be checked. They are capable of outputting the acquired static images to a processing device after acquisition.

Device Description

The DRX-Revolution Mobile X-ray system will support the new Lux HD Detectors with the DEC function (K243556), additionally the detectors will also support the optional SNC feature (K241505).

Carestream Mobile X-ray Systems
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. It is a mobile diagnostic system intended to generate and control X-rays for examination of various anatomical regions.

Lux HD Detectors (35x43, 43x43 sizes)
Lux HD 35x43 and 43x43 detectors are high-definition detectors (100um) designed with a Cesium Iodide scintillator for the conversion from X-ray to visible photon. The visible photons are transformed to electron signals by a diode capacitor array within TFT panel, which are composed and processed by connecting to scanning and readout electronics to form an image by transmitting to the device PC through the user interface. The CsI scintillator provides a high spatial resolution image.
The detectors use a glass free technology which makes the overall detector weight lighter and mitigates the risks related to device breakage. Lux HDs are designed with Digital Exposure Control (DEC) functionality which uses a wireless connection to communicate with a DEC control box, which in turn connects to the generator for x-ray control. This DEC feature also enables AEC functions to be used for mobile imaging without a physical wired connection. These detectors will integrate into the DRX-Revolution X-ray system

DRX-LC Detector
DRX-LC digital flat panel detector is a large-sized X-ray flat panel detector with wireless function based on amorphous silicon (a-Si) thin film transistor (TFT) technology. It utilizes a cesium iodide (CsI)

scintillator, and a 3064×8696 active pixel matrix with a pixel size of 139μm, providing high-quality radiographic images.
The DRX-LC is designed with DEC feature (same as above) using two additional accessories to support DEC function, a wireless control box and wireless transmission adapter. This detector will integrate into the DRX-Revolution X-ray system.

Table 1: DRX-Revolution Mobile X-ray System

Component	Predicate: DRX-Revolution Mobile X-ray System (K241505)	Reference: DRX-Evolution Plus X-ray System, DRX-Compass X-ray System, Lux HD 35 Detector, Lux HD 43 Detector (K250954)	Modified: DRX-Revolution Mobile X-ray System (K253185)	Evaluation
Compatible Digital Flat Panel Detectors	DRX Plus 3543C, 4343C (K153142) DRX Plus 2530C (K183245) Lux 35 Detector (K203159)	Lux HD 35 (K243556) Lux HD 43 (K243556) DRX-LC (K230059)	Lux HD 35 (K243556) Lux HD 43 (K243556) DRX-LC (K230059)	Lux HD DQE/MTF data are similar; any differences confirmed by verification and validation testing and do not impact image quality. The detectors being added are previously cleared detectors sold on the US market.
DR Application System Software	ImageView Software v2.0 with SNC	Same	Same	ImageView version 2.0 cleared in K250954 and K241505 and remains unchanged in this submission. Minor change to the GUI to support DEC, does not impact safety and/or performance.
X-Ray Tube(s)	Toshiba/XRR-3336X	Same	Same	No impact to safety or performance.
X-ray Generator	Carestream Generator (32kW)	Same	Same	No impact to safety or performance.
Exposure Control	No	Yes Digital Exposure Control (DEC) is introduced (integrated) into the Lux HD detectors.	Yes Digital Exposure Control (DEC) is introduced (integrated) into the Lux HD detectors.	Verification and validation testing confirm introduction of DEC feature does not raise any new questions of safety or effectiveness.

Summary of Technological Characteristics

The modified DRX-Revolution (K241505) system is substantially equivalent to the predicate device currently cleared on the market. The modifications include the integration of the new Lux HD digital flat panel detectors and inclusion of the SNC and DEC features and are described below.

- The cleared Lux HD detectors with Digital Exposure Control (DEC) functionality were cleared in a detector-level submission by Carestream's development partner under K243556 and then subsequently transferred to Carestream for device listing. Carestream's version of the detector is the same with the only difference being minor optimization. The DRX-LC was cleared in K230059 for use with general radiography and for use with DEC feature. All of the above detectors with DEC function will be compatible with the mobile system.

- The digital radiography systems (DRX-Revolution Mobile X-Ray System) that will support the cleared Lux HD detectors consist of the same fundamental scientific technology and is designed with the same operating principles as the predicate devices. The predicate and modified system consist of the same critical components: an x-ray generator, x-ray tube, collimator, and image acquisition software. The only difference is the minor modification to the acquisition software to support the detectors with DEC functionality.

- The ImageView software is the image acquisition software that is installed on the digital x-ray systems. The base version of the software (2.0) has been cleared with the following Carestream DR systems
  - DRX Evolution Plus (K233381)
  - DRX Compass (K223842)
  - DRX-Revolution (K241505)
  - DRX-Evolution Plus X-ray System, DRX-Compass Mobile X-ray System with Lux HD 35 Detector, Lux HD 43 Detector Detectors (K250954)

The image processing software (Eclipse II) includes the optional Smart Noise Cancellation (SNC) module and is the same as the predicate devices. *SNC is not installed on the detectors. It is important to note that the image processing software and the imaging chain remains the same, we are only adding cleared detectors, Lux HD 35, Lux HD 43 (K243556), and DRX-LC for use with the previously cleared Eclipse II w/SNC.

Smart Noise Cancellation clearances:

- Eclipse II with Enhanced Noise Reduction (K202441)
- Eclipse II SNC Claims (K213307)
- DRX-Revolution (K241505)
- DRX-Evolution Plus (K233381)
- DRX-Compass (K223842)
- DRX-Evolution Plus X-ray System, DRX-Compass Mobile X-ray System with Lux HD 35 Detector, Lux HD 43 Detector (K250954)

Summary of Clinical Testing

A clinical study was designed to evaluate the image quality performance of SNC on images acquired from the Carestream Focus HD 35/43 and Lux HD 35/43 detectors. Performance testing included imaging performance of the Eclipse II (rendering software) with and without Smart Noise Cancellation, capturing images with the Focus HD 35/43 and Lux HD 35/43 detectors for use on mobile and stationary systems. Images were obtained from 7 mobile systems at 8 different sites and acquired using live subjects, anthropomorphic phantoms, and adult cadaveric specimens. All processed images were delivered to a diagnostic workstation with high-resolution monitors for comparative evaluation by board-certified radiologists. The study demonstrated that images processed with SNC are equivalent to or better than images processed without SNC (the predicate device). The following key points summarize the outcomes of the testing for the in-rooms systems:

- Overall preference is in favor of SNC at a meaningful level ($p = 0.000$).
- Image quality for SNC is as good as or better than images without SNC ($p = 0.000$), regardless of image type, with a mean RadLex score of 3.4 ("Diagnostic"), which supports the claim of SNC being safe and effective. Greater than 99.7% of the SNC RadLex images were rated the same as or higher than the non-SNC images.
- SNC produces images with hardware appearance as good as or better than the predicate device.
- A CDRAD phantom was used to compare images acquired at nominal dose without SNC to images generated at 50% reduced dose with SNC, which produced similar scores of inverse Image Quality Figure (IQFinv).
- A reader study conducted by four independent, board-certified diagnostic radiologists compared pairwise live patient images acquired at nominal dose without SNC to simulation-generated images representing approximately 50% dose reduction processed with SNC. Actual live patient images acquired at reduced dose were not obtained or evaluated; therefore, the comparison was limited to simulated reduced-dose images and did not include a direct comparison using real patient images acquired at reduced exposure. The study demonstrated that simulated reduced-dose images processed with SNC were of diagnostic quality comparable to nominal-dose images processed without SNC based on RadLex ratings.

The claim below is cleared and applicable to the mobile system.

- "SNC provides improved diagnostic quality, preservation of fine detail and better contrast-to-noise ratio for images acquired at clinically nominal exposures. SNC enables customers to lower radiation dose without loss in image quality".

  **These statements were validated using Carestream CsI detectors in reader studies conducted by board-certified radiologists. Pairwise comparisons were performed between images at nominal exposure dose without SNC and at 50% reduced dose with SNC. The reduced-dose images included live patient images with simulated dose reduction, as well as images of human cadavers and anthropomorphic phantoms obtained using actual reduced-dose X-ray exposures. SNC performance was further confirmed using a CDRAD phantom. IEC EI values on average at nominal and reduced doses were 220 and 110, respectively."*

Summary of Non-Clinical Testing

System verification and validation was performed. This testing demonstrates the safety and performance of the new Lux HD detectors integrated with the DRX-Revolution system.
Additional IQ testing was performed, which specifically characterizes SNC performance using quantitative methods of analysis of non-clinical data. The "predicate" device processed images without SNC, and the "subject" device processed images with SNC. The predicate and subject devices were evaluated using captures of flat fields and physics phantoms. The images from both devices were quantitatively compared using Normalized Noise Power Spectra (NNPS), standard deviation (noise) of flat sections of the images, Modulation Transfer Function (MTF), and the contrast-detail curve.
This testing demonstrated that there is significant noise reduction without impacting sharpness and resulting in retention of image spatial resolution between the predicate and subject devices."

Performance Standards & FDA Guidance Documents

The following FDA guidance documents were reviewed prior to the 510(k) submission.

- Content of Premarket Submissions for Device Software Functions *Guidance for Industry and Food and Drug Administration Staff* June 2023
- Cybersecurity in Medical Devices: Quality System Considerations and Content of Premarket Submissions, June 27, 2025
- Pediatric Information for X-ray Imaging Device Premarket Notifications *Guidance for Industry and Food and Drug Administration Staff* November 2017

The following performance standards are applicable to the DRX-Revolution Mobile X-ray system:

- ISO 14971:2019 Application of risk management to medical devices
- ISO 20417:2021 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

- IEC 63000:2018: Technical documentation for the assessment of electrical and electronic products with respect to the restriction of hazardous substances
- Digital Imaging and Communication in Medicine (DICOM)