January 20, 2026

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

Re: K250954
Trade/Device Name: DRX-Evolution Plus X-ray System, DRX-Compass X-ray System, Lux HD 35 Detector, Lux HD 43 Detector
Regulation Number: 21 CFR 892.1680
Regulation Name: Stationary X-Ray System
Regulatory Class: Class II
Product Code: KPR, MQB
Dated: December 19, 2025
Received: December 19, 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 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 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)*
K250954

Device Name
DRX-Evolution Plus X-ray System, DRX-Compass X-ray System, Lux HD 35 Detector, Lux HD 43 Detector

Indications for Use *(Describe)*

DRX-Evolution Plus X-ray System
The device is indicated for use in obtaining diagnostic quality radiographic images to aid the physician with diagnosis. The system can be used to perform radiographic imaging of various portions of the human body, including the skull, spinal column, extremities, chest, abdomen and other body parts. The device is not indicated for use in mammography.

DRX-Compass X-ray System
The device is indicated for use in obtaining diagnostic quality radiographic images to aid the physician with diagnosis. The system can be used to perform radiographic imaging of various portions of the human body,including the skull, spinal column, extremities, chest, abdomen, and other body parts. The device is not indicated for use in mammography.

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.

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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510(k) Summary K250954

510(k) Owner Name	Carestream Health, Inc.
510(k) Owner Address	150 Verona St, Rochester, New York, 14608
510(k) Owner Contact Information	Gina Maiolo
Phone (Mobile)	516 395 0597
Date Summary Prepared	January 16, 2026
Device Trade Name(s)	DRX-Evolution Plus X-ray System DRX-Compass X-ray System Lux HD 35 Detector Lux HD 43 Detector
Device Common Name(s)	Stationary X-Ray System, Solid State X-ray Imager (Flat Panel/Digital Imager)
Classification Name(s)	Stationary X-ray System
Device Class	Class II
Device Code(s)	KPR, MQB
Regulation Number(s)	21 CFR 892.1680
Predicate Device(s)	Lux HD Detectors (K243556) DRX-Evolution Plus X-ray System (K233381) DRX-Compass X-ray System (K223842)

Indications for Use

DRX-Evolution Plus X-ray System
The device is indicated for use in obtaining diagnostic quality radiographic images to aid the physician with diagnosis. The system can be used to perform radiographic imaging of various portions of the human body, including the skull, spinal column, extremities, chest, abdomen and other body parts. The device is not indicated for use in mammography.

DRX-Compass X-ray System
The device is indicated for use in obtaining diagnostic quality radiographic images to aid the physician with diagnosis. The system can be used to perform radiographic imaging of various portions of the human body,including the skull, spinal column, extremities, chest, abdomen, and other body parts. The device is not indicated for use in mammography.

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.

Device Description

Lux HD Digital Flat Panel Detectors (35x43, 43x43 sizes)
Lux HD 35x43 and 43x43 detectors are high-definition detectors (100um) designed with a Cesium Iodide (CsI) 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 which helps to increase the diagnostic confidence. 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 with out-of-bucky exams and mobile imaging without a physical wired connection.

Carestream In-Room X-ray Systems

The DRX Evolution Plus (K233381), DRX Compass (K223842) are permanently installed diagnostic x-ray systems for general radiographic x-ray imaging. These systems consist of a combination of components including an x-ray generator, workstation computers, various models of patient support tables, wall-mounted image receptors/detectors for upright imaging, various models of tube support devices, x-ray tube, and collimator (beam-limiting device). Currently, the DRX Evolution Plus X-ray system is designed to use a standalone automatic exposure control (AEC) chamber placed in front of the detector to control the x-ray exposures. Lux HD will be compatible with these systems. The DRX-Compass will not support the DEC feature; however the Lux HD detectors can still be used for general radiography.

Table 1. Lux HD SE Table

	Lux HD 35x43 Lux HD 43x43 (K243556-predicate device -iRay LLC)	**Lux HD 35x43 Lux HD 43x43 (subject device-Carestream Inc.)**	**Evaluation**
Size	386 x 460 x 15 mm 460 x 460 x 15 mm	384 x 460 x 14.4 mm 460 x 460 x 14.4 mm	Same
Scintillator	Cesium Iodide (CsI)	Cesium Iodide (CsI)	Same
Substrate	Glass reinforced epoxy laminate (non-glass)	Glass reinforced epoxy laminate (non-glass)	Same
Panel Design	TFT	TFT	Same
DEC Functionality	Yes	Yes	Same
Pixel Pitch	100 microns	100 microns	Same
AD Conversion	16 bits	16 bits	Same
Detector Resolution	3,500 x 4,300 pixels 4,300 x 4,300 pixels	3,500 x 4,300 pixels 4,267 x 4,267 pixels	Same
Image Capture Area (usable pixel area)	35.0 cm x 43.0 cm 43.0 cm x 43.0 cm	35.0 cm x 43.0 cm 42.7 cm x 42.7 cm	Same
Sensitivity, RQA-5 Beam	680 to 867 LSB/µGy	680 to 867 LSB/µGy	Same
Minimum DQE @ 2.5 µGy, RQA-5 Beam	68% @ 0.08 cyc/mm 54% @ 1.0 cyc/mm 39% @ 2.0 cyc/mm 27% @ 3.0 cyc/mm 16% @ 4.0 cyc/mm 8% @ 5.0 cyc/mm	68% @ 0.08 cyc/mm 54% @ 1.0 cyc/mm 39% @ 2.0 cyc/mm 27% @ 3.0 cyc/mm 16% @ 4.0 cyc/mm 8% @ 5.0 cyc/mm	Same
MTF, RQA-5 Beam	> 65 % @ 1.0 cyc/mm Typical: 73% @ 1.0 cyc/mm	> 65 % @ 1.0 cyc/mm Typical: 73% @ 1.0 cyc/mm	Same

Table 2: DRX-Evolution Plus and DRX Compass X-ray Systems

Component	DRX Evolution Plus System (K233381) DRX-Compass System	DRX Evolution Plus System DRX Compass System	Evaluation
Compatible Digital Flat Panel Detectors	**Evolution:** • DRX Plus 2530 (K183245) • Focus HD 35 (K213646) • Focus HD	New detectors with DEC feature • Lux HD 35 (K243556) • Lux HD 43 (K243556)	Lux HD integration testing with the DR systems passed and is provided in this submission.
	Compass: • DRX Plus 2530 (K183245) • Focus HD 35 (K213646) • Focus HD 43 (K213529)	New detectors without DEC feature • Lux HD 35 (K243556) • Lux HD 43 (K243556)	*Compass will not support the DEC feature, however it will be compatible with Lux HD for general radiography purpose only.
DR Application System Software	ImageView Software v2.0 with SNC	Same	Verification and Validation confirms integration of detectors does not raise any new questions of safety or effectiveness.
Radiographic	Radiographic Table	Same	No impact to safety or performance
X-Ray Tube(s)	**Evolution:** Canon XRR-4631G, Varex	Same	No impact to safety or performance
	Compass: Toshiba (Canon): E7254FX, E7252X		
X-ray Generator	**Evolution**: Three Phase, CGN-80 (65kW	Same	No impact to safety or performance
	Compass: Three Phase, CGF-50-2, CGF- 50-3, CGF-65-3, and		
Exposure Control	**Evolution**: Analog Automatic Exposure Control (AEC) chambers AEC is integrated inside the wall and table buckies, only support exams	**Evolution:** Same. 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. As noted above, *Compass will not support the DEC feature, however it will be compatible with Lux HD for general radiography purpose only.
	Compass: No AEC feature	**Compass:** No Digital Exposure Control (DEC)	

Summary of Safety and Performance

Technological Characteristics

The modified DRX-Evolution Plus (K233381), DRX-Compass (K223842) systems are substantially equivalent to the predicate devices currently cleared on the market. The below key points support this determination and summarizes the similarities in characteristics when comparing the modified and predicate devices. Any minor differences do not raise questions on performance or safety in regards to the radiographic systems.

- 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 digital radiography systems 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 systems 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
  - K233381 (DRX Evolution Plus)
  - K223842 (DRX Compass System)

ImagweView 2.0 (B2.2) supports the digital radiography rooms systems (DRX Compass, DRX Evolution Plus) with the Lux HD detectors with DEC, SNC and Smart Virtual LLI features. The Smart Virtual LLI feature is built on top of the existing cleared LLI functionality. It is designed to enhance (not replace) the operator's workflow by providing an optimized starting point for LLI exams for the technologist. Instead of relying on the existing (cleared) LLI default settings, Smart Virtual LLI intelligently suggests the initial parameter for the regions (top, bottom, collimation width, and OID), allowing for more efficiency in adjustments.

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), Focus HD 35, Focus HD 43 (K213646, K213529) 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 Evolution Plus (K233381)
- DRX Compass (K223842)

Clinical and Non 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 stationary systems. Images were 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 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 of 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 the images acquired at nominal dose without SNC to the images generated at 50% reduced dose images with SNC which produced similar scores of inverse of Image Quality Figure (IQF_{inv}).

- 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.

System verification and validation was performed. This testing demonstrates the safety and performance of the new Lux HD detectors integrated with the DRX-Evolution and DRX-Compass systems.

Additional IQ testing was performed, which specifically characterizes the 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 the 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 the subject devices.

In conclusion both clinical and non-clinical (bench) testing demonstrates the DRX Evolution and DRX Compass systems (modified) with integration of the Lux detectors with DEC and SNC is the same as or equivalent to the cleared room systems (predicate) currently on the market.