Carestream Health, Inc.   April 2, 2021
℅ Gina Maiolo
Sr. Manager Regulatory Affairs, Clearance & Surveillance
150 Verona Street
ROCHESTER NY 14608

Re: K202441
    Trade/Device Name: Eclipse II with Smart Noise Cancellation
    Regulation Number: 21 CFR 892.1680
    Regulation Name: Stationary x-ray system
    Regulatory Class: Class II
    Product Code: MQB
    Dated: February 16, 2021
    Received: February 19, 2021

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); 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,

Michael D. O'Hara For

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

Indications for Use

510(k) Number *(if known)*
K202441

Device Name
Eclipse II with Smart Noise Cancellation

Indications for Use *(Describe)*
"The software performs digital enhancement of a radiographic image generated by an x-ray device. The software can be used to process adult and pediatric x-ray images. This excludes mammography 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.

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510(k) Summary

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
	email: gina.maiolo@carestream.com
Phone (Work)	585.627.6543
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Date Summary Prepared	March 30 2021
Device Trade Name	Eclipse II with Smart Noise Cancellation
Device Common Name	Solid State X-Ray Imager
Device Class	Class II
Product Code	MQB
Regulation Number	21 CFR 892.1680
Regulation Description	Stationary X-ray system
Predicate Device	Eclipse II 510(k) K180809

Carestream Health, Inc. is submitting this Traditional 510(k) premarket notification for modifications to the Eclipse II with Smart Noise Cancellation. Carestream believes that the modified device is substantially equivalent to the cleared device (K180809).

Indications for Use
"The software performs digital enhancement of a radiographic image generated by an x-ray device. The software can be used to process adult and pediatric x-ray images. This excludes mammography applications."

Device Description
Eclipse software runs inside the ImageView product application software (also namely console software). The Eclipse image processing software II with Smart Noise Cancellation is similar to the predicate Eclipse image processing software (K180809). Eclipse with Smart Noise Cancellation is an optional feature that enhances projection radiography acquisitions captured from digital radiography imaging receptors (Computed Radiography (CR) and Direct Radiography (DR). The modified software is considered an extension of the

software (it is not stand alone and is to be used only with the predicate device). The subject device supports the Carestream DRX family of detectors, this includes all CR and DR detectors. The primary difference between the predicate and the subject device is the addition of a Smart Noise Cancellation module. The Smart Noise Cancellation module consists of a Convolutional Neural Network (CNN) trained using clinical images with added simulated noise to represent reduced signal-to-noise acquisitions. Eclipse with Smart Noise Cancellation (modified device) incorporates enhanced noise reduction prior to executing Eclipse II image processing software.

Technological Characteristics

Eclipse software enhances projection radiography acquisitions captured from digital radiography imaging receptors (Computed Radiography (CR) and Direct Radiography (DR) which is the same as the predicate software K180809. The software was modified to include the support for Smart Noise Cancellation. This Smart Noise Cancellation module consists of a Convolutional Neural Network (CNN), trained using clinical images with added simulated noise to represent reduced signal-to-noise acquisitions. The main difference between the modified and predicate device is the Smart Noise Cancellation module only. The comparison chart below demonstrates the similarities to further support that the overall image processing architecture is the same between the predicate and modified device.

- Both the predicate and modified device is software designed for the enhancement of the raw images captured from the digital flat panel detectors (detectors have obtained separate clearances). The enhancement image processing intends to present an image with proper image quality attributes (brightness, latitude, overall contrast and detail, sharpness, and noise appearance) for the purpose of helping radiologists and physicians to make a diagnosis (same as the predicate).

- The difference in the modified software is the implementation of noise suppression prior to enhancement processing. The Smart Noise Cancellation operation passes the acquired preprocessed image through a specially trained Convolutional Neural Network (CNN) based on a U-Net architecture to generate a 2D map of the estimated noise found in the image, identified in the document as a "Noise Field." This change does not raise new questions regarding safety and effectiveness.
  Risks were assessed in accordance to ISO 14971 and evaluated and reduced as far as possible with risk mitigations and mitigation evidence.

- The modifications to the ImageView software, (acquisition software for digital radiography systems) has been modified to enable/disable the Eclipse II with Smart Noise Cancellation. These user interface changes are described in detail in the Substantial Equivalence discussion and do not introduce new risks or raise new questions pertaining to safety and effectiveness.

- The difference in image processing paths between the predicate and modified device demonstrate that the noise level in images processed thru the modified software (Eclipse II with Smart Noise Cancellation) is greatly reduced when compared with the image processed thru the predicate software, Eclipse II.

Summary of Non-Clinical Testing
There are two non-clinical testing reports to demonstrate substantial equivalence.

- The report for the Analysis of the Difference Images is the difference of the images processed with the investigational software (Eclipse II with Smart Noise Cancellation) and the predicate software (Eclipse II). The report focused on the analysis of the residual image artifacts. In conclusion, the images showed no substantial residual edge information within regions of interest.

- The report for the Ideal Observer Evaluation is based on simulated lesions on chest images. The evaluation demonstrated that detectability is preserved or improved with the investigational software for all supported detector types and exposure levels tested.

  A complete list of the supported detectors:
  - DRX Plus 3543 & DRX Plus 4343 (K150766), DRX-L (GOS) (K190611)
  - DRX Plus 3543C & DRX Plus 4343C (K153142), Lux 3543C (CsI) (K203159)
  - DRX Plus 2530C (K183245)
  - Carestream DRX-1 System w/DRX-1 Detector (K090318)
  - DRX-1C (K120062), DRX 2530C (CsI) (K130464)

Summary of Clinical Testing
A clinical evaluation was performed by board certified radiologists.
The images were evaluated using a 5-point visual difference preference scale (-2 to +2) tied to diagnostic confidence. Additionally, the overall diagnostic capability of each image was evaluated using the 4-point RadLex scale. The statistical test results and graphical summaries demonstrate that the investigational software delivers diagnostic quality images that exceed the quality of the predicate software over a range of exams, detector types and exposure levels.

Conclusion of Testing
The software modifications do not significantly affect fundamental design, technology, device materials, or packaging. Additionally, the investigational and predicate are substantially equivalent as a result of the following:
- The performance of the investigational software is the same as or better than the predicate software.
- The differences within the software do not raise new or different questions of safety and effectiveness.
- The intended use for both the investigational and predicate software remain the same.

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

Attribute	Eclipse II Predicate Device (K180809)	Eclipse II with Smart Noise Cancellation (K202441)
Indications for Use	"The software performs digital enhancement of a radiographic image generated by an x-ray device. The software can be used to process adult and pediatric x-ray images. This excludes mammography applications."	same
Grid Suppression	Analysis for and removes grid frequencies from the image.	same
Image Segmentation	Image analysis that identifies the anatomy of interest by detecting direct exposure and collimator blades.	same
Recognition	Optional tech assist features on chest exams that provide auto-orientation (head-up), identify clipped lung bases and provide a CNR image quality metric.	same
Parameter Prediction	Automatic determination of rendering parameters based upon features extracted from histograms of the image in support of (4) to (10) frequency bands.	same
Enhanced Noise Reduction Support	no	yes
Rendering (frequency decomposition and enhancement)	(4) to (10) frequency bands.	**same**