January 14, 2022

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

Re: K213307
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: December 10, 2021
Received: December 13, 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,

Laurel Burk
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)*
K213307

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

K213307

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 (Work)	585.627.6543
Phone (Mobile)	516.395.0597
Date Summary Prepared	Sept 30 2021

Device Trade Name	Eclipse II with Smart Noise Cancellation
Device Common Name	Solid State X-Ray Imager
Classification Name	Stationary X-ray system
Device Class	Class II
Device Code	MQB
Regulation Number	21 CFR 892.1680
Predicate Device	Eclipse II 510(k) 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."

Device Description

Eclipse software runs inside the ImageView product application software (not considered stand-alone software). Smart Noise Cancellation is an optional feature (module) that enhances projection radiography acquisitions captured from digital radiography imaging receptors (Computed Radiography (CR) and Digital Radiography (DR). Eclipse II with Smart Noise Cancellation supports the Carestream DRX family of detectors which includes all CR and DR detectors.

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 II with Smart Noise Cancellation incorporates enhanced noise reduction prior to executing Eclipse image processing software. The software has the capability to lower dose up to 50% when processed through the Eclipse II software with SNC, resulting in improved image quality. A 50% dose reduction for CsI panel images and 40%

dose reduction for GOS panel images when processed with Eclipse II and SNC results in image quality as good as or better than nominal dose images

Technological Characteristics

The technological characteristics of the Eclipse II with Smart Noise Cancellation remain the same. Reference the Comparison Table for a summary of changes.

Eclipse II software enhances projection radiography acquisitions captured from digital radiography imaging receptors (Computed Radiography (CR) and Digital Radiography (DR) which is the same as the predicate software K202441. 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 predicate and modified.

- 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.

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Summary of Non-Clinical Testing

No additional non-clinical testing was required to demonstrate substantial equivalence between the predicate device labeling and the modified labeling.

Summary of Clinical Testing

A concurrence study was performed by board certified radiologists in accordance with FDA “Guidance for the Submission of 510(k)s for Solid State X-ray Imaging Devices" and Carestream standard procedure for concurrence studies and Carestream standard procedure for concurrence studies.

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 RadLexscale. The statistical test results and graphical summaries demonstrate that the software delivers diagnostic quality images at 50% dose reduction for CsI panel images and 40% dose reduction for GOS panel reduced radiation doses that are equivalent to or exceed the quality of nominal dose images over a range of exams, detector types and exposure levels.

Conclusion of Testing

Clinical testing validates the modifications to the device description.

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

	Predicate (K202441)	**Subject Device**
Trade Name	Eclipse II with Smart Noise Cancellation	same
Manufacturer	Carestream Health	same
Indications for Use	"The software performs digital enhancement of a adiographic 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	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

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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	Yes	same
Device Description	Eclipse software runs inside the ImageView product application software (not considered stand-alone software). Smart Noise Cancellation is an optional feature (module) that enhances projection radiography acquisitions captured from digital radiography imaging receptors (Computed Radiography (CR) and Digital Radiography (DR). Eclipse II with Smart Noise Cancellation supports the Carestream DRX family of detectors which includes all CR and DR detectors. 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 II with Smart Noise Cancellation incorporates enhanced noise reduction prior to executing Eclipse image processing software.	Addition: The software has the capability to lower dose up to 50% when processed through Eclipse II SNC, resulting in improved image quality. A 50% dose reduction for CsI panel images and 40% dose reduction for GOS panel images when processed with Eclipse II and SNC results in image quality as good as or better than nominal dose images