Carestream Health, Inc
Diane Koetter
Sr. Manager, Regulatory Affairs and Quality Systems
150 Verona Street
Rochester, New York 14608

June 21, 2018

Re: K180809
Trade/Device Name: Eclipse II
Regulation Number: 21 CFR 892.1680
Regulation Name: Stationary x-ray system
Regulatory Class: Class II
Product Code: MQB
Dated: March 23, 2018
Received: March 28, 2018

Dear Diane Koetter:

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820);

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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/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

Robert A. Ochs, Ph.D.
Director
Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K180809

Device Name
Eclipse II

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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Carestream

"510(k) Summary"

510(k) Owner Name:	Carestream Health, Inc.
510(k) Owner Address:	150 Verona Street Rochester, New York 14608
510(k) Owner Phone:	585-627-6505
510(k) Owner Fax:	585-627-8802
Contact Person & Info:	Diane Koetter Sr. Manager, Regulatory Affairs and Quality Systems diane.koetter@carestream.com 585-627-6505
Date Summary Prepared:	June 18, 2018
Device Trade Name:	Eclipse II
Device Common Name:	Solid State X-Ray Imager (Flat Panel/Digital Imager)
Classification Name:	Stationary x-ray system
Device Class:	Class II
Device Code:	MQB
Regulation Number:	21 CFR 892.1680
Predicate Devices:	Kodak Eclipse Image Processing Software Manufactured by: Eastman Kodak Company 510(k) No.: K060137 (March 16, 2006)

Device Description:

The Eclipse II image processing software, like the original Eclipse image processing software, enhances projection radiography acquisitions captured from digital radiography imaging receptors (computed radiography (CR) and direct radiography (DR)).

The original Eclipse image processing software used a 4 band frequency decomposition method to enhance the output image. By comparison, the Eclipse (subject) image processing software uses 4 or more band frequency decomposition method. The additional number of bands allows for flexibility in frequency adjustments.

Indications for Use / Intended Use:

The Indications for Use for the device, as described in its labeling, are:

> "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."

The intended use for this device, as determined by descriptions and the proposed labeling contained in this submission, is similar to the Indications for Use statement provided above.

The subject device's proposed Indications for Use are different from the predicate device. The indications for K060137 are outdated as the statement refers primarily to a computed radiography base product. Therefore, this traditional 510(k) for Eclipse II is proposing an entirely new Indication for Use statement for the modified software device. The proposed Indications for Use of the subject device fall within the Intended Use of the predicate device and can be considered for substantial equivalence. Any variation in features or technical specifications have been identified and addressed through testing (described below) to support a substantial equivalence determination.

Comparison of Technological Characteristics:

Based upon information provided within this submission, we believe that the Eclipse II is substantially equivalent to the legally marketed Eclipse (predicate device). The Eclipse II image processing software, like the original Eclipse image processing software, enhances projection radiography acquisitions captured from digital radiography imaging receptors (computed radiography (CR) and direct radiography (DR)).

The image processing chain is the same for both the predicate and the subject devices. It involves segmenting the image into anatomically relevant image areas and decomposing the image into frequency bands. The frequency bands are enhanced and recombined resulting in the production of an improved diagnostic quality image. The original Eclipse (predicate) software utilizes a 4 frequency band decomposition method. The Eclipse II (subject) software uses a 4 or more frequency band decomposition method. The additional number of bands allows for flexibility in frequency adjustments.

Discussion of Testing

The performance characteristics and operation / usability of the Eclipse II software were evaluated in non-clinical (bench) testing. These studies demonstrated the intended workflow, related performance, overall function, verification and validation of requirements for intended use, and reliability of the software. Non-clinical test results have demonstrated that the device conforms to its specifications.

A clinical Reader Study was performed. Results of the Reader Study demonstrate that the Eclipse II Software provides diagnostic quality images.