Carestream Health, Inc.
% Ms. Diane Koetter
Sr. Manager, Regulatory Affairs and Quality Systems
150 Verona Street
ROCHESTER NY 14608

April 13, 2018

Re: K180667
Trade/Device Name: SmartGrid
Regulation Number: 21 CFR 892.1680
Regulation Name: Stationary x-ray system
Regulatory Class: II
Product Code: MQB
Dated: March 12, 2018
Received: March 14, 2018

Dear Ms. 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 the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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 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)*
K180667

Device Name
SmartGrid

Indications for Use *(Describe)*
"SmartGrid feature is a software option that provides, upon request by user, a diagnostic radiograph image with a reduction in visible x-ray scatter similar to the effect of an anti-scatter grid."

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:	April 11, 2018
Device Trade Name:	SmartGrid
Device Common Name:	Flat Panel Digital Detector System
Classification Name:	Stationary x-ray system
Device Class:	II
Device Code:	MQB
Regulation Number:	21 CFR 892.1680
Predicate Device:	SmartGrid Manufactured by: Carestream Health, Inc. 510(k) No.: K163157 (March 21, 2017)

Please Note: The marketing name for the modified SmartGrid device is not expected to change. The modified device is referred to as "SmartGrid II" within this submission for clarity.

Device Description:

The SmartGrid II software is designed to improve contrast and reduce the appearance of scatter in radiographic images that have been acquired without a physical grid. SmartGrid II encapsulates an algorithm for estimating and removing scatter from radiographic images.

The SmartGrid II software feature is accessible through the DirectView application software. Users will be able to select SmartGrid II processing before an image is acquired, or to change whether SmartGrid II processing is applied to a previously acquired image.

Indications for Use / Intended Use:

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

"SmartGrid feature is a software option that provides, upon request, a diagnostic radiograph image with a reduction in visible x-ray scatter similar to the effect of an anti-scatter grid."

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 Indications for Use for the subject device is the same as for the predicate device and the intended use remains unchanged. 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 SmartGrid II software is substantially equivalent to the legally marketed SmartGrid (predicate device).

SmartGrid II has the same technological characteristics as SmartGrid (predicate device). Both are optional software components that allow for reduction in visible x-ray scatter in radiographic images.

Both devices use:

- Scatter Factor Estimation
- Scatter Correction
- Noise Reduction and Image Rendering

The predicate device differs from the investigational device in the methods used for Scatter Estimation and Scatter Correction. For instance, the original SmartGrid feature estimated and corrected scatter based on the exposed area within the collimation field. SmartGrid II estimates and corrects scatter based on the full detector field rather than the collimated sub-region. In addition, the SmartGrid and SmartGrid II algorithms differ slightly to further improve the scatter estimation and correction.

Discussion of Testing:

The performance characteristics and operation / usability of the SmartGrid 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. Predefined acceptance criteria were met and demonstrated that the device is as safe, as effective, and performs as well as or better than the predicate device.

Specifically, the following "bench" testing was performed as described below:

- Installation testing was performed to verify successful installation of the SmartGrid II software component onto the representative system.
- Specific test cases were implemented to verify that SmartGrid II image processing consistently produces a diagnostic quality image
- Specific test cases were implemented to verify that image noise was sufficiently reduced and image contrast/brightness were sufficient for clinical diagnosis
- Regression testing was performed using manual and automated test case execution
- Integration tests were performed to ensure proper performance of the SmartGrid II software feature when integrated into the Carestream application software
- Error handling was observed for proper function through monitoring of event logs
- Ad Hoc testing was performed as considered applicable to help ensure no unexpected negative effects

In addition to bench testing, existing clinical research images processed with both the original SmartGrid and SmartGrid II software were evaluated by a board certified radiologist. This clinical evaluation was intended to confirm no unexpected negative effects with respect to diagnostic image quality associated with the use of the improved algorithm. The reader study demonstrated that images processed with SmartGrid II were equivalent in diagnostic quality to images processed with the predicate device, SmartGrid.

Summary:

The differences between SmartGrid II and the predicate device do not affect the intended use of the device or alter the fundamental scientific technology of the device. Performance testing results support a substantial equivalence determination of SmartGrid II to the predicate device.

FDA Reference Materials:

The following FDA guidance documents were consulted in the development of the SmartGrid II software feature:

- General Principles of Software Validation – Final Guidance for Industry and FDA Staff; issued 01/11/2002
- Off-The-Shelf Software Use in Medical Devices – Guidance for Industry and FDA Reviewers, and Compliance; issued 09/09/1999
- Content of Premarket Submissions for Management of Cybersecurity in Medical Devices – Guidance for Industry and Food and Drug Administration Staff; issued 10/02/2014
- Deciding When to submit a 510(k) for a Software Change to an Existing Device – Guidance for Industry and Food and Drug Administration Staff; issued 10/25/2017
- Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices; issued 05/11/2005