DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

March 21, 2017

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

Re: K163157
Trade/Device Name: SmartGrid
Regulation Number: 21 CFR 892.1680
Regulation Name: Stationary x-ray system
Regulatory Class: II
Product Code: MQB
Dated: March 13, 2017
Received: March 15, 2017

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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K163157

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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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:	November 8, 2016
Device Trade Name:	SmartGrid
Device Common Name:	Flat Panel Digital Detector System
Classification Name:	Stationary x-ray system
Device Class:	Class II
Device Code:	MQB
Regulation Number:	21 CFR 892.1680
Predicate Device:	FDR D-EVO Flat Panel Detector System (DR-ID600) Manufactured by FujiFilm Medical Systems USA, Inc. 510(k) No. – K141765 (October 3, 2014)

Device Description:

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

The SmartGrid feature is accessible through DirectView DR Product application software. Users will be able to select SmartGrid processing before an image is

acquired, or to change whether SmartGrid processing is applied to a previously acquired image.

Indications for Use / Intended Use:

The Indications for Use for the SmartGrid Software is:

"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."

Comparison of Technological Characteristics:

SmartGrid Software has the same technological characteristics as the predicate device, FDR D-EVO Flat Panel Detector System (DR-ID600). Both are optional software components that allow for reduction in visible x-ray scatter in radiograph images.

Discussion of Testing:

The performance characteristics and operation of SmartGrid (investigational) were evaluated in a radiologist reader study. It was not possible to obtain the predicate device images. Therefore, images of cadaveric specimens and phantoms were acquired and used in the study.

The SmartGrid software performance was compared against two reference systems. In one reference system, images were acquired with grids at 400 speed exposure (grid reference) and processed with the Carestream DirectView V5.7 software (K060137). In the second reference system, images were acquired without grids at 400 speed exposure (non-grid reference) and processed with the same DirectView V5.7 software.

Radiologists reviewed and rated investigational and reference images (both grid and non-grid), for diagnostic quality, using a Radlex subjective diagnostic rating scale. The results demonstrate:

- SmartGrid processing software produces diagnostic quality images.
- At all exposure levels, SmartGrid processing produced images rated as good as or better than the non-grid reference images.
- SmartGrid processing software produces images with statistically equivalent diagnostic quality at lower exposures than the grid reference acquisitions.

Substantial Equivalence:

The proposed predicate device, FDR D-EVO Flat Panel Detector System (DR-ID600), has been found substantially equivalent by FDA through the 510(k) process (K141765) and is legally marketed. Its Indications for Use, though not

identical to the SmartGrid, convey similar information about the intended use of the device and can therefore be considered for substantial equivalence.

Both devices utilize:

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

Both devices depend on the proper estimation of the scatter-to-primary ratio (SPR) to calculate scatter distribution and perform image enhancement. In both applications, the user can adjust SPR if desired.

Both devices suppress noise.

The predicate device differs from the investigation device in the methods for scatter estimation, scatter distribution and noise control.

The differences between SmartGrid and the predicate device do not affect the intended use of the device or alter the fundamental scientific technology of the device. Performance testing and clinical results support a substantial equivalence determination of the SmartGrid to the FDR D-EVO Flat Panel Detector System (DR-ID600).