



Food and Drug Administration
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Silver Spring, MD 20993-0002

Carestream Health, Inc.
% Ms. Victoria Wheeler
Sr. Regulatory Affairs Manager, US&C
150 Verona Street
ROCHESTER NY 14608

November 25, 2015

Re: K153142

Trade/Device Name: Carestream DRX-1 System with DRX Plus 4343 Detectors
Regulation Number: 21 CFR 892.1680
Regulation Name: Stationary x-ray system
Regulatory Class: II
Product Code: MQB
Dated: November 5, 2015
Received: November 6, 2015

Dear Ms. Wheeler:

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,

A handwritten signature in black ink that reads "Robert Ochs". The signature is written in a cursive style with a grey shadow effect behind the text.

Robert Ochs, Ph.D.
Director
Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known)

K153142

Device Name

Carestream DRX-1 System

Indications for Use (Describe)

The device is intended to capture for display radiographic images of human anatomy including both pediatric and adult patients. The device is intended for use in general projection radiographic applications wherever conventional screen-film systems or CR systems may be used. Excluded from the indications for use are mammography, fluoroscopy, and angiography 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 Phone: 585 627-8706
510(k) Owner Fax: 585 627-8802

Contact Person & Info: Victoria Wheeler
Sr. Regulatory Affairs Manager, US&C
victoria.wheeler@carestream.com
585-627-8706

Date Summary Prepared: October 21, 2015

Device Trade Name: Carestream DRX-1 System w/ DRX Plus 4343
Detectors
Device Common Name: Flat Panel Digital Imager
Classification Name: Stationary x-ray system

Device Class: Class II
Device Code: MQB
Regulation Number: 21 CFR 892.1680

Predicate Device: Carestream DRX-1 System (with DRX Plus
3543 Detectors)
Manufactured by: Carestream Health, Inc.
510(k) No.: K150766 (June 24, 2015)
Classification Regulation: 21 CFR 892.1680
Classification Name: Stationary x-ray system
Primary Product Code: MQB

Device Description:

The Carestream DRX-1 System is a diagnostic imaging system utilizing digital radiography (DR) technology that is used with diagnostic x-ray systems. The system consists of the Carestream DRX-1 System Console (operator console), flat panel digital imager (detector), and optional tether interface box. The system can be configured to register and use any of the two new DRX-Plus 4343 and DRX Plus 4343C Detectors. Images captured with a flat panel digital detector can be communicated to the operator console via tethered or wireless connection.

Indications for Use / Intended Use:

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

“The device is intended to capture for display radiographic images of human anatomy including both pediatric and adult patients. The device is intended for use in general projection radiographic applications wherever conventional screen-film systems or CR systems may be used. Excluded from the indications for use are mammography, fluoroscopy, and angiography 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 Carestream DRX-1 System with DRX Plus 4343 and DRX Plus 4343C Detectors is a diagnostic imaging system utilizing digital radiography (DR) technology that is used to capture x-rays for diagnostic procedures. We believe that the Carestream DRX-1 System with DRX Plus 4343 and DRX Plus 4343C Detectors and the predicate device have the same intended use.

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 Carestream DRX-1 System with DRX Plus 4343 and DRX Plus 4343C Detectors is substantially equivalent to the legally marketed Carestream DRX-1 System with the DRX Plus 3543 Detectors (predicate device). Both the currently marketed DRX Plus 3543 Detectors and the new DRX Plus 4343 and DRX Plus 4343C Detectors are used in combination with the image processing software and user interface resident on the DRX-1 System Console component of the Carestream DRX-1 System. The system is used to directly capture conventional projected x-rays to generate digital images, regardless of which detector is being used. An image can be displayed on a preview monitor for viewing with any of the detectors. The system can transmit diagnostic images through a digital network for diagnostic viewing and printing regardless of which detector is used.

The predicate (DRX Plus 3543/3543C) Detectors share synonymous design specifications except the larger physical size of the detector (43cmX43cm).

Discussion of Testing:

The performance characteristics and operation / usability of the Carestream DRX-1 System with DRX Plus 4343 and DRX Plus 4343C Detectors were evaluated in non-clinical (bench) testing in accordance with FDA guidance document “Guidance for the Submission of 510(k)’s for Solid State Imaging Devices”.

Non-clinical test results have demonstrated that the device conforms to its specifications. Acceptance criteria were determined based on desired performance with respect to image quality, intended use, workflow related performance, shipping performance, and general

functionality and reliability, including both hardware and software requirements. 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; therefore supporting a substantial equivalence determination. Acceptance criteria were identified for weight, pixel size, resolution, pixel pitch, total pixel area, usable pixel area, MTF (at various spatial resolutions), DQE (at various spatial resolutions), sensitivity, ghosting, boot-up time, operating temperature, exposure latitude, signal uniformity, and dark noise (ADC). 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.

Clinical studies were not submitted because the non-clinical data was sufficient to demonstrate substantial equivalence to the predicate device.

Consensus Standards:

The device conforms to ISO 14971:2012, Digital Imaging and Communications in Medicine (DICOM) Set, IEC 60601-1+Amd 1 - 3rd Edition 2005, CFR 47 part 15, ANSI C95.1, and IEC 60601-1-2:2007.

Compatibility:

Carestream has a documented validation and verification process for integrating the Carestream DRX-1 System and DRX Plus 4343 and DRX Plus 4343C Detectors with OEM x-ray consoles that were originally installed by other manufacturers as analog or computed radiography x-ray systems. The modifications made to the existing x-ray system are limited to integration between the hand-switch and its connector to the x-ray system console. Sales and service personnel are qualified to determine whether the Carestream DRX-1 System can be integrated with a particular x-ray system. Once installed, proper operation is verified before the system is turned over for use on patients.

As of March 21, 2013, the systems listed in the Compatibility List (Table 1) have been found compatible with the Carestream DRX-1 System. This list may be updated in the future to include additional compatible systems.

CARESTREAM DRX-1 System Compatibility List

Bennett Model HFQ-12050P	Philips Diagnost 94	DEL ATC 525
CPI CMP	Philips Easy Diagnost Eleva	DEL ATC 725
CPI Indico 100	Odyssey	Dyna RAD
CPI Indico 100 RAD	Quantum (Odyssey HF Series)	GE AMX4
DEL AXR	Quantum Q-Vision	GE MPG 50
Fischer RMS Digital 425HF	Rontgenwerk Editor Mp	GE MPG 65
GE 500D	Sedecal Shf-330	GE MPS 64
GE Advantx	Shimadzu Gsc	GE MVP 80
GE MPG	Siemens Axiom Dr	GE Silhouette VR
GE MPH	Siemens Fluorospot Compact	Gendex Reliance ATC525
GE MVP	Philips Optimus	Gendex Reliance ATC725
GE Precision RXi	Philips Super Cp	Medira 2000
GE Prestige II	Picker Mtx	Philips Medio CP

GE Prestilix 1600X	Picker Rad 65	Picker Clinx-R
GE Proteus	Primax Go	Quantum Quest
GENDEX APG500	Primax/Mecal Challenger	Reliance ATC725
GMM Opera	Siemens Polydoros	Sedecal Global
KODAK DIRECTVIEW DR 5100	Siemens Polydoros 80s	Sedecal Ideal
KODAK DIRECTVIEW DR 7100	Siemens Polydoros Gen It55	Sedecal SHF
KODAK DIRECTVIEW DR 3500	Siemens Polydoros Lx	Sedecal Touchscreen
KODAK DIRECTVIEW DR 7500	Siemens Polydoros Sx	Shimadzu Evolution
KODAK DIRECTVIEW DR 9000	Stephanix Trophy N500	Siemens Mobile XP Hybrid
KODAK DIRECTVIEW DR 9500	Suinsa Hercules	Siemens Mobilette
Quantum	Toshiba Kalare	Stadler Electronik AG SE 4500
Philips Diagnost 93	Toshiba Kxo	

Table 1

The Beam Detect Mode allows integration with OEM systems where there is no access to intercept the Prep/Expose signal. The user commands the detector to get prepared for an exposure on the Carestream DRX-1 System Console and separately asserts the “expose” command to the x-ray generator when the Console indicates the detector is ready. The detector determines when an exposure has arrived and captures the image.

Conclusion:

In conclusion, the new detectors are equivalent to the DRX Plus 3543 Detectors in all applicable parameters recommended by the Guidance for the Submission of 510(k)’s for Solid State Imaging Devices. Image quality parameters such as DQE, sensitivity, and MTF of the DRX Plus 4343 and DRX Plus 4343C Detectors demonstrate this. The tests used to determine these parameters were performed using industry standards.

The new detectors have been tested to conform to applicable existing specifications of the predicate DRX Plus 3543 Detectors. Quality Assurance tests with traceable links to design inputs were performed to verify conformance to specifications. In addition, tests were included to confirm mitigation of risks identified in an extensive product hazard risk analysis based on results of a Failure Mode Effects Analysis.