K090318
Page 1 of 2

Carestream HEALTH

Attachment 9

Carestream DRX-1 System

510(k): Carestream Health, Inc.

510(k) Summary
Prepared in accordance with 21 CFR Part 807.92(c)

APR - 6 2009

Submitter: Carestream Health, Inc.
150 Verona Street
Rochester, New York 14608

Contact Person: Christine Ehmann
Regulatory Affairs Director
Telephone: 585-627-6473; Fax: 585-454-1894

Date Prepared: February 6, 2009

Device Name: Carestream DRX-1 System
21 CFR 892.1650 MQB

Equivalent Device (currently marketed): Kodak DirectView CR 850 System, 510k number: K020635

Device Description: The Carestream DRX-1 System is a digital imaging system to be used with diagnostic x-ray systems. It includes a Carestream DRX-1 System Detector (flat panel digital detector), Carestream DRX-1 System Console (operator console) and Carestream DRX-1 System Interface Box (generator interface or Interface Box). Images captured with the flat panel digital detector can be communicated to the operator console via tethered connection or wireless.

Indications for Use: The Carestream DRX-1 System is intended to capture for display radiographic images of human anatomy. It 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, tomography and angiography applications.

Comparison with Predicate Device: The Kodak DirectView CR 850 System (CR 850) and the Carestream DRX-1 System are digital imaging systems. Each device is used to acquire radiographic images digitally. The CR 850 system and the Carestream DRX-1 System, both, differ from traditional X-ray film systems in that instead of exposing a film for subsequent wet chemical processing to create a hardcopy image for viewing, a digital image is used to display and reviewing in electronic form. The digital data are then used to produce softcopy images to be sent to a hardcopy printing device or archive device. The CR 850 System reads the x-ray image captured on stimulated phosphor screens and converts it to a digital image. The Carestream DRX-1 System Detector is used to directly capture and convert conventional projected X-ray images to digital images. An image can be displayed on a preview monitor for viewing on both devices. The diagnostic image can be transmitted through a digital network for diagnostic viewing and printing using both devices.

Summary of Evaluation: Performance testing was conducted to verify the design output met the design input requirements and to validate the Carestream DRX-1 System conformed to the defined user needs and intended uses. Non-clinical testing was conducted under simulated use conditions. Predefined acceptance criteria was met and demonstrated that the Carestream DRX-1 System is as safe, as effective, and performs as well as or better than the predicate device. The Carestream DRX-1 System has been evaluated for product safety, electromagnetic compatibility and radiation safety. It conforms to applicable medical device safety standards.

Carestream HEALTH

Attachment 9

Clinical Testing: Results of clinical testing demonstrated there were no significant differences observed between the Kodak DirectView CR 850 System and Carestream DRX-1 System with respect to clinical acceptance or the ability to diagnose.

Conclusion: The Carestream DRX-1 System is designed and will be manufactured in compliance with ISO 13485, the Quality System Regulations for Medical Devices and 21 CFR Part 820. The Carestream DRX-1 System is in conformance with applicable international and national safety standards. Based on the results of the clinical and bench testing, product comparison, product safety and electromagnetic compatibility testing, Carestream Health, Inc. concludes that the Carestream DRX-1 System is substantially equivalent to the current Kodak DirectView CR 850 System.

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room – WO66-G609
Silver Spring, MD 20993-0002

AUG 23 2013

Ms. Christine Ehmann
Regulatory Affairs Manager
Carestream Health, Inc.
150 Verona Street
ROCHESTER NY 14608

Re: K090318
Trade/Device Name: Carestream DRX-1 System
Regulation Number: 21 CFR 892.1680
Regulation Name: Stationary x-ray system
Regulatory Class: II
Product Code: MQB
Dated: February 6, 2009
Received: February 9, 2009

Dear Ms. Ehmann:

This letter corrects our substantially equivalent letter of April 6, 2009.

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.

If your device is classified (see above) into class II (Special Controls), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. 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 Parts 801 and 809); medical device reporting (reporting of

medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Parts 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. 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 Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely Yours,

Janine M. Morris
Acting Director
Division of Radiological Devices
Office of In Vitro Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Statement of Indications for Use

510(k) Number (if known): K090318

Device Name: Carestream DRX-1 System

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Concurrence of CDRH, Office of Device Evaluation

Prescription Use ✓ OR Over-the counter use _____
(per 21 CFR 801.109)

(Division Sign-Off)
Division of Reproductive, Abdominal and Radiological Devices
510(k) Number K090318