K120062

Carestream

APR 13 2012

"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:	585 627-6543
510(k) Owner Fax:	585 454-1894
Contact Person & Info:	Carolyn Wagner Regulatory Affairs Manager, Medical Imaging carolyn.wagner@carestream.com 585-627-6588
Date Summary Prepared:	January 5, 2011
Device Trade Name:	DRX-Revolution Mobile X-ray System
Device Common Name:	mobile x-ray system
Classification Name:	Mobile x-ray system
Device Class:	Class II
Device Code:	IZL
Regulation Number:	21 CFR 892.1720
Predicate Device:	Shimadzu MobileDaRt Manufactured by Shimadzu Corp. 510(k) No. – K041763 (July 13, 2004)

Device Description:

The DRX-Revolution Mobile X-ray System (also referred to as the DRX-Revolution) is a diagnostic mobile x-ray system utilizing digital radiography (DR) technology. The DRX-Revolution consists of a self contained x-ray generator, image receptor(s), imaging display and software for acquiring medical diagnostic images outside of a standard stationary x-ray room. The DRX-Revolution system incorporates a flat-panel detector that can be used wirelessly for exams such as in-bed chest projections. The system can also be used to expose CR phosphor screens or film.

Indications for Use / Intended Use:

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

"The device is designed to perform radiographic x-ray examinations on all pediatric and adult patients, in all patient treatment areas."

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 DRX-Revolution is a mobile system used to generate and control x-rays for diagnostic procedures. We believe that the DRX-Revolution and the predicate device have the same intended use.

The Indications for Use for the subject device is different than the predicate device, but these differences do not alter the intended diagnostic use of the device. Differences are appropriately characterized as descriptive, 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:

The DRX-Revolution Mobile X-ray System is substantially equivalent to the predicate device, the Shimadzu MobileDaRt (MUX-100D). The DRX-Revolution Mobile X-ray System and the Shimadzu MobileDaRt system both consist of an x-ray generator, x-ray tube, collimator, and graphical user interface on an operator console with touch screen monitor. These components are mounted on a motorized cart that is battery powered to enable the device to be moved from location to location. Both systems utilize a digital flat panel detector for image capture and can also be used to expose CR storage phosphor or film cassettes. Both systems have operator console software with image processing capability.

Discussion of Testing

The performance characteristics and operation / usability of the DRX-Revolution system 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, shipping performance, and reliability of the DRX-Revolution system including both software and hardware requirements. 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.

A concurrence study of clinical image pairs was performed in accordance with FDA guidance document "Guidance for the Submission of 510(k)'s for Solid State Imaging Devices" to demonstrate the diagnostic capability of the DRX-Revolution system. Results of the Reader Study indicated that the diagnostic capability of the DRX-Revolution Mobile X-ray System is statistically equivalent to or better than that of the predicate device. These results support a substantial equivalence determination.

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

Ms. Carolyn Wagner
Regulatory Affairs Manager
Carestream Health, Inc.
150 Verona Street
ROCHESTER NY 14608

APR 13 2012

Re: K120062
Trade/Device Name: DRX-Revolution Mobile X-ray System
Regulation Number: 21 CFR 892.1720
Regulation Name: Mobile x-ray system
Regulatory Class: II
Product Code: IZL
Dated: March 2, 2012
Received: March 5, 2012

Dear Ms. Wagner:

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

Indications for Use

510(k) Number (if known):

Device Name: DRX-Revolution Mobile X-ray System

Indications for Use:

The device is designed to perform radiographic x-ray examinations on all pediatric and adult patients, in all patient treatment areas.

Prescription Use X AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

(Division Sign-Off)
Division of Radiological Devices
Office of In Vitro Diagnostic Device Evaluation and Safety

510K K120062