Carestream HEALTH

K091889

JUL 20 2009

"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
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Contact Person & Info:	Carolyn Wagner Regulatory Affairs Manager, Medical Imaging carolyn.wagner@carestreamhealth.com 585-627-6588
Date Summary Prepared:	May 20, 2009
Device Trade Name:	DRX-Evolution
Device Common Name:	diagnostic x-ray system
Classification Name:	Stationary x-ray system
Device Class:	Class II
Device Code:	90 KPR
Regulation Number:	21 CFR 892.1680
Predicate Devices:	Kodak DirectView DR 7500 Manufactured by Carestream Health, Inc. 510(k) No. – K051258 (June 1, 2005) AND Carestream DRX-1 System Manufactured by CarestreamHealth, Inc. 510(k) No. – K090318 (April 6, 2009)

Device Description:

The DRX-Evolution is a diagnostic x-ray system utilizing digital radiography (DR) technology. The DRX-Evolution is designed for horizontal and upright projections. It consists of a high frequency x-ray generator, overhead tube crane (with x-ray tube assembly), elevating 4-way float radiographic table with detector tray, tilting Bucky receptor on an upright Wall Stand, and x-ray controls containing a power distribution unit and operator PC. The DRX-Evolution incorporates the following new features:

- Add the wireless Carestream DRX-1 System detector option as a component of the x-ray system
- Include a different model CPI generator
- Add a Toshiba x-ray tube option (tube used in predicate device (K051258) still available)
- Include Carestream- designed motion control software that functions the same as the OEM-designed motion control software used in the predicate device (K051258).

Intended Use:

The DRX-Evolution system is a permanently installed diagnostic x-ray system for generation of x-rays for examination of various anatomical regions.

Comparison of Technological Characteristics:

The DRX-Evolution has the same technological characteristics as the predicate device, the Kodak DirectView DR 7500 System. The DRX-Evolution System incorporates various configurations with the following standard components: radiographic table, flat panel detector, x-ray generator, x-ray tube housing, and beam-limiting device. The device modifications raise no new issues of safety or effectiveness.

Discussion of Testing

Performance testing was conducted to verify the design output met the design input requirements and to validate the device conformed to the defined user needs and intended uses. Nonclinical testing was conducted under simulated use conditions. Predefined acceptance criteria was met and demonstrated that the device is as safe, as effective, and performs as well as or better than the predicate device.

Substantial Equivalence Comparison with Predicate Devices

	Kodak DirectView DR 5100	Kodak DirectView DR 7100	Kodak DirectView DR 7500	DRX-Evolution
DR System	K001341	K001341	K051258 (SE to Kodak DirectView DR 5100/7100)	SE to Kodak DirectView DR 7500 (K051258) and Carestream DRX-1 System (K090318)
Image Processing Software	K925344	K925344	K925344, K060137	K060137
Long Length Imaging Software	No	No	K081836	K081836
Intended Use & Indications for Use	Permanently installed diagnostic x-ray system for generation of x-rays for examinations of various anatomical regions.	Permanently installed diagnostic x-ray system for generation of x-rays for examinations of various anatomical regions.	Permanently installed diagnostic x-ray system for generation of x-rays for examinations of various anatomical regions.	Permanently installed diagnostic x-ray system for generation of x-rays for examinations of various anatomical regions.
X-ray Generator	Communication Power Industries Indico 100 Series X-ray Generator	Communication Power Industries Indico 100 Series X-ray Generator	Communication Power Industries Indico 100 Series X-ray Generator	Communication Power Industries CMP200DR X-ray Generator
X-ray Tube	Varian X-ray Tube (RAD-60 w/ B-130 housing)	Varian X-ray Tube (RAD-60 w/ B-130 housing)	Varian X-ray Tube (RAD-60 w/ B-130 housing)	Varian X-ray Tube (RAD-60 w/ B-130 housing) / Alternate: Toshiba E7254GX with XH-157 Housing
Beam Limiting Device	Collimator: Huestis Medical Model 150 PBL	Collimator: Huestis Medical Model 150 PBL	Collimator: Ralco, Model 302 ACS . Collimator K / Alternate: Ralco R302 DACS/A	Ralco R302 DACS/A
Detector	DirectRay Digital Array & Controller (Solid State Digital Device, K973206)	DirectRay Digital Array & Controller (Solid State Digital Device, K973206)	DirectRay Digital Array & Controller (Solid State Digital Device, K973206) / Alternate: Trixell Pixium 4600 Digital Detector	Carestream DRX-1 Digital Detector (K090318) / Alternate: Trixell Pixium 4600 Digital Detector
Operator Console (X-ray control)	Diagnostic Operator Console • System software w/ image processing capability • Computer w/ touch screen monitor • Barcode Scanner	Diagnostic Operator Console • System software w/ image processing capability • Computer w/ touch screen monitor • Barcode Scanner	Diagnostic Operator Console • System software w/ image processing capability • Computer w/ touch screen monitor • Barcode Scanner	Diagnostic Operator Console • System software w/ image processing capability • Computer w/ touch screen monitor • Barcode Scanner
Timing Distribution Unit (X-ray control)	Timing and Distribution Unit: Best Power Fortress 750 UPS	Timing and Distribution Unit: Best Power Fortress 750 UPS	Timing and Distribution Unit (provides generator interface & power distribution): Best Power Fortress 750 UPS / Alternate: APC 1500 VA UPS	Power Distribution Unit (provides power distribution & generator interface): Optional APC 1500 VA UPS
Overhead Tube Crane / Tube Stand	Tube Stand w/ manual and automated x-ray tube assembly movement	Overhead Tube Crane w/ manual x-ray tube assembly movement	Overhead Tube Crane w/ manual and automated x-ray tube assembly movement	Overhead Tube Crane w/ manual and automated x-ray tube assembly movement
Wall Stand	Yes, contains Bucky w/ Detector	No	Yes, contains Bucky w/ Detector	Yes, contains Bucky w/ Detector
Table	No	Yes, contains Bucky w/ Detector	Yes, contains Bucky w/ Detector	Yes, contains Bucky w/ Detector

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 20 2009

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

Re: K091889
Trade/Device Name: DRX-Evolution
Regulation Number: 21 CFR 892.1680
Regulation Name: Stationary x-ray system
Regulatory Class: II
Product Code: KPR
Dated: June 23, 2009
Received: June 24, 2009

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 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 go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 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/cdrh/mdr/ 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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Janine M. Morris
Acting Director, Division of Reproductive, Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Statement of Intended Use

510(k) Number (if known): K091889

Device Name: DRX-Evolution

Indications for Use: The DRX-Evolution system is a permanently installed diagnostic x-ray system for generation of x-rays for examination of various anatomical regions.

Prescription Use____X____ AND/OR Over-The-Counter Use_____

(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal and Radiological Devices
510(k) Number K091889