

Carestream

JUN 11 2013

“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: 585-323-7643

Contact Person & Info: Carolyn Wagner
Regulatory Affairs Manager, Medical Imaging
carolyn.wagner@carestreamhealth.com
585-627-6588

Date Summary Prepared: June 5, 2013

Device Trade Name: DR Long Length Imaging Software
Device Common Name: DR digital imager
Classification Name: Solid state x-ray imager (flat panel/digital imager)

Device Class: Class II
Device Code: MQB
Regulation Number: 21 CFR 892.1650

Predicate Devices: Cedara I-Softview™ (Accustitch™ component)
Manufactured by Cedara Software Corp.
510(k) No. – K022881 (October 22, 2002)

Kodak Eclipse Image Processing Software
Manufactured by Carestream Health, Inc.
510(k) No. – K060137 (May 16, 2006)

Device Description:

The DR Long Length Imaging Software is a software component for use on a diagnostic x-ray system utilizing digital radiography (DR) technology. The software option is comprised of image stitching software and a manual stitch editor that allows user adjustment to automatic stitching results. The software allows up to 5 separately acquired DR images to be stitched together to create a “composite” long length image.

Indications for Use / Intended Use:

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

“The software’s intended use is to allow post-capture positioning and joining of individual images to produce an additional composite image. The software is sold only for use on Carestream Health system solutions and is available as an integrated feature within the DirectView software.”

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 DR Long Length Imaging software component provides the ability to perform operations related to image manipulation and enhancement of medical images. We believe that the DR Long Length Imaging software and the predicate devices 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 software component. 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 DR Long Length Imaging Software has the same technological characteristics as the predicate device, the Cedara I-Softview “Accustitch” component. The DR Long Length Imaging Software is an optional software component that allows a composite image to be formed from up to five separately acquired general radiography images. It is available as an integrated optional feature within the predicate device Kodak Eclipse Image Processing Software (DirectView software). The software device raises 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. Clinical testing was conducted to evaluate the acceptability of the composite images for diagnostic use. Predefined acceptance criteria were met and demonstrated that the device is as safe, as effective, and performs as well as the predicate device.



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

June 11, 2013

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

Re: K130567

Trade/Device Name: DR Long Length Imaging Software
Regulation Number: 21 CFR 892.1650
Regulation Name: Solid State X-Ray Imager (Flat Panel/Digital Imager)
Regulatory Class: Class II
Product Code: MQB
Dated: May 7, 2013
Received: May 10, 2013

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. 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.

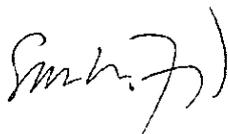
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's 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 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/MedicalDevices/ResourcesforYou/Industry/default.htm>. 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/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/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,



for

Janine M. Morris
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): K130567

Device Name: DR Long Length Imaging Software

Indications for Use:

The software's intended use is to allow post-capture positioning and joining of individual images to produce an additional composite image. The software is sold only for use on Carestream Health system solutions and is available as an integrated feature within the DirectView software.

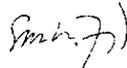
Prescription Use x
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of *In Vitro* Diagnostics and Radiological Health (OIR)



(Division Sign-Off)
Division of Radiological Health
Office of *In Vitro* Diagnostics and Radiological Health

510(k) K130567