



Food and Drug Administration
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Carestream Health, Inc.
Carolyn Wagner
Sr. Supervising Manager, Regulatory Affairs & Quality Systems
150 Verona Street
Rochester, New York 14608

August 30, 2016

Re: K160723
Trade/Device Name: OnSight 3D Extremity System
Regulation Number: 21 CFR 892.1750
Regulation Name: Computed Tomography X-Ray System
Regulatory Class: Class II
Product Code: JAK
Dated: July 22, 2016
Received: August 1, 2016

Dear Carolyn 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 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 blue ink that reads "Michael D. O'Hara". The signature is written in a cursive style and is positioned to the left of the printed name.

FOR

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)

Device Name

OnSight 3D Extremity System

Indications for Use (Describe)

The device is intended to be used for x-ray computed tomography and projection x-ray imaging of upper and lower extremities of adult patients and pediatric patients aged 12 and over.

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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“510(k) Summary”

510(k) Owner Name: Carestream Health, Inc.
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Contact Person & Info: Carolyn Wagner
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carolyn.wagner@carestream.com
585-627-6588

Date Summary Prepared: March 15, 2016

Device Trade Name: OnSight 3D Extremity System
Device Common Name: Computed Tomography X-ray System
Classification Name: Computed tomography x-ray system

Device Class: Class 2
Device Code: JAK
Regulation Number: 21 CFR 892.1750

Predicate Device Trade Name: Planmed Verity
Manufactured by: Planmed Oy
510(k) No.: K121418 (February 1, 2013)

Device Common Name: Computed Tomography X-ray System
Classification Name: Computed tomography x-ray system

Device Class: Class 2
Device Code: JAK
Regulation Number: 21 CFR 892.1750

Device Description:

The Carestream Health OnSight 3D Extremity System is a medical x-ray imaging device designed to acquire three-dimensional, volumetric CT data of patient extremities (feet, ankles, lower leg, knees, hands, wrists, arms and elbows). The device is configured as a “cone beam computed tomography” system (CBCT) in that the x-ray field covers the whole anatomy of interest (~25cm in length) and the data is acquired with a single rotation of the detector and x-ray source (actually a short scan of

180 degrees plus “fan angle” for a total of 216.5 degrees) with no patient motion through the irradiation field. The device is intended for use in a range of different locations including office-based medical practice, hospital departments and other imaging facilities. The system is also capable of acquiring standard two-dimensional projection radiographs of the same body parts.

Indications for Use / Intended Use:

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

“The device is intended to be used for x-ray computed tomography and projection x-ray imaging of upper and lower extremities of adult patients and pediatric patients aged 12 or over.”

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 OnSight 3D Extremity System is a computed tomography x-ray system (cone beam CT) used to generate 2D and 3D digital images of upper and lower extremities for diagnostic procedures. We believe that the OnSight 3D Extremity System and the predicate device (Planned Verity) 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 OnSight 3D Extremity System is substantially equivalent to the legally marketed Planned Verity (predicate device). Both the Planned Verity and OnSight 3D systems utilize Cone Beam Computed Tomography (CBCT) techniques to create a 3 dimensional reconstruction of a patient’s upper or lower extremity. Both devices are designed as standalone units which enable the complete patient imaging procedure from acquisition of the x-ray images through patient information management, image processing and archiving of to be performed. Both systems image a single extremity at a time and support weight bearing imaging of the foot/ankle, leg or knee, in addition to the “non-loaded” imaging of these and the upper extremities (hand, wrist, arm and elbow).

Both systems utilize an amorphous silicon flat panel detector (a-Si:H) to acquire a multitude of 2-D projection x-rays sequentially acquired as the detector and x-ray source rotate around the patient’s anatomy. During the acquisition of the multiple exposures the x-ray tube is pulsed (rather than continuous radiation). The duration of the complete scan is 20-25 seconds for the OnSight 3D device.

Discussion of Testing

The performance characteristics and operation / usability of the OnSight 3D Extremity 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, and reliability of the 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 clinical study was performed to demonstrate the diagnostic capability of the OnSight 3D Extremity System. Since it was not possible to obtain clinical images from the Planned Verity system, two reference devices were used for comparison. The Philips Brilliance CT X-ray system (K060937) was used to evaluate 3D images. The DRX-1C Detector (K120062) as a component of the DRX-Evolution x-ray system (K091889) was used as a comparison to evaluate the 2D images.

Results of the Reader Study indicated that the diagnostic capability of the OnSight 3D Extremity System is statistically equivalent to or better than that of the reference devices.

Conclusions

Both the Planned Verity and OnSight 3D Extremity System utilize Cone Beam Computed Tomography (CBCT) techniques to create a 3 dimensional reconstruction of a patient's upper or lower extremity. Both devices are designed as standalone units which enable the complete patient imaging procedure from acquisition of the x-ray images through patient information management, image processing and archiving to be performed. Both systems image a single extremity at a time and support weight bearing imaging of the foot/ankle, leg or knee, in addition to the "non-loaded" imaging of these and the upper extremities (hand, wrist, arm and elbow).

Both systems utilize an amorphous silicon flat panel detector (a-Si:H) to acquire a multitude of 2-D projection x-rays sequentially acquired as the detector and x-ray source rotate around the patient's anatomy. During the acquisition of the multiple exposures the x-ray tube is pulsed (rather than continuous radiation). This multitude of projection images is then processed by advanced software algorithms to generate a 3-dimensional representation of the patient's anatomy, in much the same way as a "slice based" computed tomography system generates a traditional CT scan of a patient. Both systems can also produce standard 2D projection radiographs of the patient's anatomy.

The differences between the OnSight 3D Extremity System and the predicate device (Planned Verity) are minimal and do not affect the intended use of the devices or alter their fundamental scientific technology.

Results of bench testing described above in the “Discussion of Testing” section demonstrate that the OnSight 3D Extremity System conforms to its specifications. Results of clinical studies (also described in the “Discussion of Testing” section above) demonstrate that the OnSight 3D Extremity System produces both 2D and 3D images of diagnostic quality that are equivalent or superior to the reference devices used in the clinical study. We believe that these results support a claim of substantial equivalence for the OnSight 3D Extremity System.