K113344

NOV 16 2012

510(k) SUMMARY

EOS imaging's sterEOS Workstation

Submitter's Name, Address, Telephone Number, Contact Person and Date Prepared

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Contact Person: Karine Chevrie

Date Prepared: November 14, 2011

Trade Name:

sterEOS Workstation

Common or Usual Name:

sterEOS Workstation

Classification:

21 C.F.R. § 892.2050; radiological image processing system

Product Code:

LLZ

Predicate Devices:

sterEOS Workstation (K080529; K090050; K101398)

Device Description:

The sterEOS Workstation is a general system for acceptance, transfer, display, storage, and digital processing of 2D X-ray images of the musculoskeletal system, including interactive 2D measurement tools.

When used with 2D X-ray images obtained with the EOS imaging's EOS System (K071546), the sterEOS Workstation provides interactive 3D measurement tools to aid in the analysis of skeletal deformities in spine and lower limbs.

Indications for Use:

The sterEOS Workstation is intended for use in the fields of musculoskeletal radiology and orthopedics in both pediatric and adult populations as a general device for acceptance, transfer, display, storage, and digital processing of 2D X-ray images of the musculoskeletal system including interactive 2D measurement tools.

When using 2D X-ray images obtained with the EOS imaging System (K071546), the sterEOS Workstation provides interactive 3D measurement tools:

- To aid in the analysis of scoliosis and related disorders and deformities of the spine in adult patients as well as pediatric patients 7 years and older. The 3D measurement tools include interactive analysis based on a model of bone structures derived from an a priori image data set from 175 patients (91 normal patients, 47 patients with moderate idiopathic scoliosis and 37 patients with severe idiopathic scoliosis), and dry isolated vertebrae data. The model of bone structures is not intended for use to assess individual vertebral abnormalities.

- To aid in the analysis of lower limb alignment and related disorders and deformities. The 3D measurement tools include interactive analysis based either on identification of lower limb alignment landmarks or as for the spine, on a model of bone structures derived from an a priori image data set. The model of bone structures is not intended for use in pediatric patients and is not intended for use to assess individual bone abnormalities. The 3D package including model-based measurements and torsion angles is indicated only for patients 15 years or older. Only the 2D/3D ruler is indicated for measurements in patients younger than 15 years old.

Technological Characteristics:

The sterEOS Workstation supports DICOM 3.0 formatted images. The sterEOS Workstation is based on the Windows 7 operating system and runs on off-the-shelf hardware. The sterEOS Workstation user interface follows typical clinical workflow patterns to process, review, and analyze digital images.

Performance Data:

Accuracy and precision of the automatic measurements computed from the 3D model of the spine in patients with Cobb's angle > 50° have been confirmed with X-ray clinical images. Results validate the interactive 3D measurement tools for a severe scoliosis assessment and demonstrate the equivalent performance of the device with conventional measurement methods performed on native X-ray images.

Substantial Equivalence:

The sterEOS Workstation expands the indications for use of the company's cleared sterEOS device to include patients with Cobb's angle > 50°. The sterEOS Workstation for the expanded indication for use is as safe and effective as the company's cleared sterEOS device (K080529, K090050, K101398). The device has the same intended uses and similar indications, technological characteristics, and principles of operation as its predicate device. The minor differences between the device and its predicate devices raise no new issues of safety or effectiveness. Performance data demonstrate that the device is as safe and effective as the company's cleared sterEOS device and, thus, is substantially equivalent.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-002

EOS Imaging
C/O Hogan Lovells US LLP
555 Thirteenth Street, NW
WASHINGTON DC 20004

NOV 16 2012

Re: K113344
Trade/Device Name: Stereos Workstation
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture Archiving and Communications System
Regulatory Class: Class II
Product Code: LLZ
Dated: October 25, 2012
Received: October 25, 2012

Dear Dr. Smith:

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 Parts 801 and 809), please contact the Office of *In Vitro* Diagnostics and Radiological Health 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,

Michael O. O'Hara 2012.11.16 11:38:07 -05'00'

Janine Morris
Director
Division of Radiological Health
Office of In Vitro Diagnostics and Radiological Health
Center for Devices and Radiological Health

Enclosure

Indications for Use Statement

510(k) Number (if known): K113344

Device Name: sterEOS Workstation

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To aid in the analysis of scoliosis and related disorders and deformities of the spine in adult patients as well as pediatric patients 7 years and older. The 3D measurement tools include interactive analysis based on a model of bone structures derived from an a priori image data set from 175 patients (91 normal patients, 47 patients with moderate idiopathic scoliosis and 37 patients with severe idiopathic scoliosis), and dry isolated vertebrae data. The model of bone structures is not intended for use to assess individual vertebral abnormalities.

To aid in the analysis of lower limbs alignment and related disorders and deformities based on angle and length measurements. The 3D measurement tools include interactive analysis based either on identification of lower limb alignment landmarks or as for the spine, on a model of bone structures derived from an a priori image data set. The model of bone structures is not intended for use to assess individual bone abnormalities. The 3D package including model-based measurements and torsion angles is indicated only for patients 15 years or older. Only the 2D/3D ruler is indicated for measurements in patients younger than 15 years old.

Prescription Use ___X__ (Part 21 C.F.R. § 801 Subpart D)

AND/OR

Over-The-Counter Use____ (21 C.F.R. § 807 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign Off)

Division of Radiological Health

Office of In Vitro Diagnostics and Radiological Health

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