K090050

510(k) SUMMARY

Biospace Med's sterEOS Workstation

MAR - 5 2010

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

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Contact Person: Karine Chevrie

Date Prepared: December 31, 2008

Trade Name:

sterEOS Workstation

Common or Usual Name:

sterEOS Workstation

Classification:

21 CFR 892.2050; radiological image processing system

Product Code:

LLZ

Predicate Devices:

sterEOS Workstation (K080529)

Device Description:

The sterEOS Workstation is a general picture archiving and communications storage 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 Biospace EOS 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.

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 PACS device for acceptance, transfer, display, storage, and digital processing of 2D X-ray images of the musculoskeletal system including interactive 2D and 3D reconstruction and measurement tools.

When using 2D X-ray images obtained with the Biospace EOS 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 in patients with a Cobb's angle > 50 degrees and is not intended for use to assess individual vertebral abnormalities.

Technological Characteristics:

The sterEOS Workstation supports DICOM 3.0 formatted images. The sterEOS Workstation is based on the Windows XP 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 studies of the 3D measurements were performed by using either anthropomorphic phantoms or patient images acquired with EOS system in hospitals. Results of these studies validate the 3D measurement tools of the software and demonstrate the equivalent performance of the device in both adult and pediatric populations.

Substantial Equivalence:

The sterEOS Workstation expands the indications for use of the company's cleared sterEOS device (K080529) to include patients 7 years and older. Performance data demonstrate that use of the device in the expanded patient population does not impact the sterEOS's safety. The modified sterEOS Workstation is otherwise identical to the cleared sterEOS Workstation. Accordingly, the sterEOS is substantially equivalent.

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

MAR - 5 2010

Biospace Med., Inc.
% John J. Smith, M.D., J.D.
Regulatory Counsel
Hogan & Hartson LLP
555 Thirteen Street, N.W.
WASHINGTON DC 20004

Re: K090050
Trade/Device Name: sterEOS Workstation
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: LLZ
Dated: November 18, 2009
Received: November 18, 2009

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 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,

Donald J. St.Pierre
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 Statement

510(k) Number (if known): _____

Device Name: sterEOS Workstation

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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)~~ (OIUD)

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

510(k) Number K090050