



Food and Drug Administration  
10903 New Hampshire Avenue  
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Silver Spring, MD 20993-0002

EOS Imaging, Inc.  
% John J. Smith, M.D., J.D.  
Regulatory Counsel  
Hogan Lovells U.S. L.L.P.  
555 Thirteenth Street, NW  
WASHINGTON DC 20004

April 22, 2016

Re: K160914  
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: April 1, 2016  
Received: April 1, 2016

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. 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. A faint, large "FDA" watermark is visible in the background behind the signature.

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)  
K160914

Device Name

sterEOS Workstation

Indications for Use (Describe)

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 EOS System, 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. The 3D measurement tools include interactive analysis based either on identification of anatomical landmarks for postural assessment or 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 for spine modeling. The model of bone structures is not intended for use to assess individual vertebral abnormalities and is indicated only for patients 7 years and older. For postural assessment, a set of comparative tools is provided allowing the comparison of performed measurements to reference values for patients over 18 years old.
- 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.

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)

**PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.**

**FOR FDA USE ONLY**

Concurrence of Center for Devices and Radiological Health (CDRH) (Signature)

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

**\*DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.\***

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*“An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number.”*

**510(k) SUMMARY**  
**EOS imaging, Inc.'s sterEOS Workstation**

EOS imaging, Inc.  
10 rue Mercoeur  
PARIS F-75011  
FRANCE

**Phone:** + 33 1 55 25 60 60

**Facsimile:** + 33 1 55 25 60 61

**Contact Person:** Mathias Breuil, Regulatory Affairs Project Leader

**Date Prepared:** April 1, 2016

**Name of Device and Name/Address of Sponsor:**

sterEOS Workstation  
EOS imaging, Inc.  
10 rue Mercoeur  
PARIS F-75011  
FRANCE

**Trade Name:** sterEOS Workstation

**Common or Usual Name:** Image processing radiological system

**Classification Name:** 21 C.F.R. 892.2050; Picture archiving and communications system  
Product Code LLZ – system, image processing, radiological

**Predicate Device:** 510(k) number: K141137  
Trade/Device Name: sterEOS Workstation  
Clearance Date: September 15, 2014  
Regulation Number: 21 CFR 892.2050  
Regulation Name: Picture archiving and communications system  
Regulatory Class: II  
Product Code: LLZ

**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 (K152788), the sterEOS Workstation provides interactive 3D measurement tools to aid in the analysis of skeletal

deformities in spine and lower limbs.

### **Intended Use/ 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 EOS System, 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. The 3D measurement tools include interactive analysis based either on identification of anatomical landmarks for postural assessment or 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 for spine modeling. The model of bone structures is not intended for use to assess individual vertebral abnormalities and is indicated only for patients 7 years and older. For postural assessment, a set of comparative tools is provided allowing the comparison of performed measurements to reference values for patients over 18 years old.
- 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.

### **Technological Characteristics**

The technological characteristics of the modified sterEOS Workstation are essentially identical to the cleared sterEOS Workstation (K141137). Like the cleared predicate, the subject device is based on the Windows 7 operating system, runs on off-the-shelf hardware, supports DICOM 3.0 formatted images, and has a user interface that follows typical clinical workflow patterns to process, review, and analyze digital images.

The main differences with the cleared sterEOS Workstation consist of the following minor software modifications:

- Addition of information in the User Manual concerning the patient position on X-ray images for the 3D modeling;
- Integration of Patient Database module to improve the sterEOS patient list performances and DICOM functionalities;

- Simplification of pelvic parameters identification;
- Reorganization of sterEOS 3D module's lower limbs workflows;
- Addition of a new clinical parameter in the global posture workflow;
- Addition of export features to allow for the transfer of sets of data for third-party applications;  
and
- Various bug corrections.

Minor hardware modifications were also made to enhance usability.

### **Performance Data**

Software modifications have been verified at the unit level. After integration, system software verification and validation testing was performed to ensure compliance with specifications, performance and non-regression. Additional performance and functional testing has confirmed the equivalent performance of the modified sterEOS Workstation compared to the predicate sterEOS.

### **Substantial Equivalence**

The device has the same intended use and indications, and very similar technological characteristics and principles of operation, as its predicate device. The minor differences between the device and its predicate raise no different questions of safety or effectiveness. Performance data demonstrate that the device is as safe and effective as the company's cleared sterEOS Workstation (K141137) and, thus, is substantially equivalent.