EOS imaging
% Mathias Breuil
Regulatory Affairs Manager
10 rue Mercoeur
Paris, 75011
FRANCE

June 19th, 2018

Re: K172346
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: June 4, 2018
Received: June 6, 2018

Dear Mathias Breuil:

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.

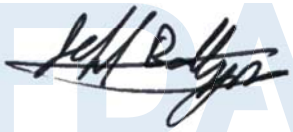
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's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

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 comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,



for
Robert A. Ochs, Ph.D.
Director
Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement on last page

510(k) Number *(if known)*

K172346

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)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510(k) SUMMARY
EOS imaging's sterEOS Workstation

EOS imaging
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FRANCE

Phone: + 33 1 55 25 60 60
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Contact Person: Mathias Breuil, Regulatory Affairs Manager

Date Prepared: July 31, 2017

Name of Device: sterEOS Workstation

Common or Usual Name: Image processing radiological system

Classification Name: 21 C.F.R. 892.2050; Picture archiving and communications system

Regulatory Class: II

Product Code: LLZ – system, image processing, radiological

Predicate Devices

510(k) number:	K160914
Clearance Date:	April 22, 2016
Device Name:	sterEOS Workstation
Classification Name:	21 CFR 892.2050, Picture archiving and communications system
Regulatory Class:	II
Product Code:	LLZ– system, image processing, radiological

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.

Summary of Technological Characteristics

The technological characteristics of the modified sterEOS Workstation are essentially identical to the cleared sterEOS Workstation (K160914). 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 subject device incorporates a revision of contra-indications related to spine modeling which has been modified as follows:

- Previous contra-indication (cleared sterEOS):
  The 3D spine modeling software may not be used in the following cases:
  - spinal columns with supernumerary vertebrae (one extra or one fewer thoracic or lumbar vertebra),
  - vertebrae with severe congenital deformities (e.g. hemivertebrae, spina bifida, etc.),
  - spondylolisthesis.

- Revised contra-indication (modified sterEOS):

  The 3D spine modeling software does not allow modeling of vertebrae with severe congenital deformities (e.g. hemivertebrae, spina bifida, etc.). The modeling of a spine including vertebrae with congenital deformities may be performed by leaving out the vertebrae with the severe congenital deformity.

The modified sterEOS also includes several minor software modifications:

- Improvement of patient report creation;
- Improvement of sterEOS 3D module launching time by replacement of Matlab runtime executable by C++ runtime executable and change of compilation process from 32 bits to 64 bits;
- Improvement of sterEOS export/import capabilities;
- Various bug corrections.

Minor hardware modifications were also made following obsolescence.

Performance Data

Revision of contraindications has been assessed through functional testing of the spine 3D modeling workflows for the no longer contraindicated types of spines: spine with extra vertebra, spine with missing vertebra, and spine with spondylolisthesis.
In addition, a functional evaluation study conducted by internal experienced radiographers from EOS imaging has been conducted to verify the ease to perform a 3D modeling and to obtain an adjusted outline of the final 3D model that matches the vertebrae of spines with extra or missing vertebrae and spines with spondylolisthesis. This functional evaluation study did not intend to provide any information related to reproducibility or reliability of 3D spine modeling and related clinical parameters.
Results showed that the revised contra-indications do not raise different safety or effectiveness concerns as with the cleared sterEOS.

Software modifications have been verified at the unit level. After integration, system software verification and validation testing were 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.

Conclusions

The modified sterEOS Workstation is as safe and effective as the cleared sterEOS Workstation (K160914). The device has the same intended uses and similar indications, technological characteristics, and principles of operation as its predicate device. In addition, the minor technological 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 Workstation (K160914) and, thus, is substantially equivalent.