510(k) SUMMARY

EOS imaging’s sterEOS Workstation

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

EOS imaging
10 rue Mercoeur
PARIS F-75011
FRANCE

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

Contact Person: Karine Chevrie
Date Prepared: Feb 01, 2011

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; K090050)
Agfa Orthopedic Software for Impax Workstations (K071972)
Device Description:

The sterEOS Workstation is a 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 EOS System (K071546), the sterEOS Workstation provides interactive 3D measurement tools to aid in the analysis of skeletal deformities in spine and lower limbs.

The sterEOS workstation is intended to be used by trained medical personnel, physicians and technologists.

Additional details about the device can be found in the table presented below in the substantial equivalence section.

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 measurement tools.

When using 2D X-ray images obtained with the EOS Imaging 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 of 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.

- 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 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 patient younger than 15 years old.

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.

A table setting forth the technological features of the sterEOS Workstation can be found in the substantial equivalence section below.
Performance Data:

Accuracy and precision of the automatic measurements computed from the 3D model of the lower limbs have been confirmed with X-ray clinical images. Results validate the interactive 3D measurement tools for lower limb assessment and demonstrate the equivalent performance of the device with conventional measurement methods performed on native X-ray images.

Substantial Equivalence:

The sterEOS Workstation for the expanded indication for use in the lower extremities is as safe and effective as the company’s cleared sterEOS device (K080529; K090050). The device has the same intended uses and similar indications, technological characteristics, and principles of operation as its predicate device. 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 device and thus, is substantially equivalent.

<table>
<thead>
<tr>
<th>Intended Use</th>
<th>Image processing system accessory to X-ray imager</th>
</tr>
</thead>
<tbody>
<tr>
<td>Indications for Use</td>
<td>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 measurement tools.</td>
</tr>
<tr>
<td></td>
<td>When using 2D X-ray images obtained with the EOS Imaging 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 years and older).</td>
</tr>
<tr>
<td></td>
<td>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 measurement tools.</td>
</tr>
<tr>
<td></td>
<td>When using 2D X-ray images obtained with the EOS Imaging 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 years and older).</td>
</tr>
<tr>
<td></td>
<td>Workstations are intended for use in the acquisition, display, digital processing, review, transfer, storage, archiving and printing of medical images and patient demographic information. They allow the user to adjust image densities (window/level), perform basic length and angle measurements and highlight regions of interest. They have the ability to use 2D, 3D and time series (cine) images and data. They are intended for use by physicians to aid in diagnosis, and by medical professionals whenever they require or desire access to medical images and patient demographic information.</td>
</tr>
<tr>
<td></td>
<td>The software application allows orthopedic surgeons and specialists to assess images, plan surgical procedures, monitor patient progress and educate patients in a digital environment. It allows assessments to be made of geometrical skeletal parameters with comparisons against normative references for adults and children in order to draw therapeutic conclusions. It includes modules for the hip, knee, spine, leg, hand, wrist, elbow, etc.</td>
</tr>
</tbody>
</table>
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.

- 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.

### User Population
- Trained medical personnel, physicians, and technologists
- Trained medical personnel, physicians, and technologists
- Trained medical personnel, physicians, and technologists

### Platform
- Off the shelf hardware
- Off the shelf hardware
- Impax workstation

### Operating System
- Windows XP
- Windows XP

### Imaging modalities
- Multimodality for 2D viewer
- EOS radiological images for 3D visualization
- Multimodality for 2D,3D viewer.

### DICOM Conformance
- DICOM 3.0
- DICOM 3.0
- DICOM 3.0

### Image type
- Monoframe image
- Monoframe image

### Hardware
- Dell Precision hardware
  - Processor: Xeon Processor
  - RAM: 2x1 GB
  - Hard Disk: 250 Go
  - Graphic card: NVIDIA Quadro (NVS 295)
  - 16X DVD +/- RW Drive
    - At least 3 external USB port connector
    - One mouse
- Dell Precision 390 hardware
  - Processor: Intel Core 2 Duo Processor
  - RAM: 2x1 GB
  - Hard Disk: 250 Go
  - Graphic card: NVIDIA Quadro FX mid-range (FX 3450)
  - 16X DVD +/- RW Drive

shoulder, foot, ankle and fractures (trauma planning). Users can access a library of manufacturers electronic templates intended to assist in the selection and positioning of implants and the marking of tissues prior to surgery.
At least 3 external USB port connector
One mouse

- EIZO Radiforce LCD
  screen size >21"
  resolution >2 million
  pixels, luminance > 200
  cd/m², response time <100 ms.

Image manipulation functions
Zoom
Magnifying glass
Pan
Grayscale inversion
Rotating flipping
Distance
Angle

Measurement functions
Distance
Angle

Workflow features
DICOM query/retrieve from archives
Multiple series loading
Annotation
DICOM print

3D reconstruction method
Lower limb 3D
reconstruction process is based on:
  - Parametric models of
    tibia and femur
  - Statistical inference
defined from database
  of clinical descriptors
  measured in 45 lower
limbs of healthy adult
subjects.
  - One morphorealist
model of lower limb
which is a meshed
volume of lower limb
regionalized as the
parametric models.

After identifying basic
anatomical landmarks,
corresponding to some
points of the parametric
models, on frontal and
lateral EOS X-ray images,
the others points of the
parametric models are
calculated by linear
regression with the
knowledge included in the a
priori data base. This
personalized parametric
model is used for adapting
the morpho-realistic
parametric meshed model
and provides a first 3D
model as close as possible
to the native X-ray contours.
This 3D model is deformed
manually by the operator
through control points up to

Spine 3D reconstruction
process is based on:
  - parametric models of
    spine and vertebrae
  - Statistical inference
defined from database
  of clinical descriptors
  measured in 175
subjects with scoliosis
and 1526 cadaveric
vertebrae.
  - One morphorealist
model of spine which is
a meshed CT volume of
spine regionalized as
the parametric models.

After identifying basic
anatomical landmarks,
corresponding to some
points of the parametric
models, on frontal and
lateral EOS X-ray images,
the others points of the
parametric models are
calculated by linear
regression with the
knowledge included in the a
priori data base. This
personalized parametric
model is used for adapting
the morpho-realistic
parametric meshed model
and provides a first 3D
model as close as possible
to the native X-ray contours.
This 3D model is deformed
manually by the operator
through control points up to

DICOM query/retrieve from archives
Multiple series loading
Annotation
DICOM print
matching accurately the X-ray contours. This deformation is performed by using common linear least squares estimation algorithm.
Biospace Med  
% Mr. John J. Smith  
Regulatory Counsel  
Hogan & Hartson L.L.P.  
555 Thirteenth Street, NW  
WASHINGTON DC 20004

Re: K101398  
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: January 14, 2011  
Received: January 14, 2011

Dear Mr. 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,

Mary Pastel, ScD.
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): K101398

Device Name: sterEOS Workstation

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 measurement tools.

When using 2D X-ray images obtained with the EOS Imaging 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.

- 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__ AND/OR Over-The-Counter Use

(Part 21 C.F.R. 801 Subpart D) (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), OIVD

(division sign-off)
Division of Radiological Devices
Office of In Vitro Diagnostic Device Evaluation and Safety

K101398