K101398

510(k) SUMMARY

FEB - 4 2011

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 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 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.

	EOS Imaging Med **sterEOS Workstation**	**EOS Imaging Med** **sterEOS Workstation K090050**	**Agfa** **Orthopedic Software for Impax workstation K071972**
Intended Use	Image processing system accessory to X-ray imager	Image processing system accessory to X-ray imager	Image processing system accessory X-ray imager
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 from 175 patients (91 normal patients, 47	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	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. 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,

	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.	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	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
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 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	

	• EIZO Radiforce LCD screen size >21", resolution >2 million pixels, luminance > 200 cd/m², response time <100 ms.	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	Zoom Magnifying glass Pan Grayscale inversion Rotating flipping	Zoom Magnifying glass Pan Grayscale inversion Rotating flipping
Measurement functions	Distance Angle	Distance Angle	Distance Angle
Workflow features	DICOM query/retrieve from archives Multiple series loading annotation DICOM print	DICOM query/retrieve from archives Multiple series loading annotation DICOM print	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 CT 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 1628 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 matching accurately the X-	

matching accurately the X-ray contours. This deformation is performed by using common linear least squares estimation algorithm.

ray contours. This deformation is performed by using common linear least squares estimation algorithm.

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

Biospace Med
% Mr. John J. Smith
Regulatory Counsel
Hogan & Hartson L.L.P.
555 Thirteenth Street, NW
WASHINTON DC 20004

FEB - 4 2011

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 S Pastel

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 patient 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

\\\DC - 026967/000001 - 3203067 v1

510K K101398