K071546

510(k) SUMMARY

Biospace Med's
EOS

SEP 18 2007

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

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Contact Person:Karine Chevrie

Date Prepared: June 5, 2007

Trade Name: EOS

Common or Usual Name: Digital Radiography System

Classification Name: Radiology

Predicate Devices

- The Lodox Digital Radiography System (K013999)
- Toshiba's Auklet CT scanner TSX-003-A (K973908)
- GE Televix 1600 (K790692) with AGFA Cornex 5 film
- Philips Bucky Diagnost System (K945278) with AGFA Curix-Ortho HT-G film
- CGR Prestilix (K843926) + Kodak DirectView CR 900 System (K020635)
- Siemens DR Thorax/Multix FD (K983732)

Intended Use / Indications for Use

The EOS is intended for use in general radiographic examinations and applications, excluding the evaluation of lung nodules and examinations involving fluoroscopy, angiography, and mammography. EOS allows the radiographic acquisition of either one or two orthogonal X-ray images for diagnostic purposes, in one single scan, of the whole body or a reduced area of investigation of a patient in the upright or seated position.

Technological Characteristics

EOS is a digital radiography system in which two sets of xenon gas filled digital detectors and X-ray tubes are positioned orthogonally to generate frontal and lateral images simultaneously. The diagnostic images are stored in a database and are displayed on a high-resolution, medical-quality monitor, where the diagnosis is performed. The diagnostic image can be transmitted through a DICOM 3.0 compatible digital network for printing and archiving. This device employs the same technological characteristics as the predicate devices differing only in the specifics of subassembly component composition.

Performance Data

EOS is designed to comply with IEC 60601-1 and collateral standards.

Additional testing confirmed the equivalent performance of the EOS as compared to the claimed predicate devices.

Substantial Equivalence

EOS is as safe and effective as conventional radiography systems. EOS has the same intended use and similar indications, technological characteristics, and principles of operation as its predicate devices. The minor technological differences between EOS and its predicate devices raise no new issues of safety or effectiveness. Performance data demonstrate that EOS is as safe and effective as common radiography systems. Thus, EOS 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

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

AUG 20 2013

Re: K071546
Trade/Device Name: EOS
Regulation Number: 21 CFR 892.1680
Regulation Name: Stationary x-ray system
Regulatory Class: II
Product Code: KPR and MQB
Dated: August 9, 2007
Received: August 10, 2007

Dear Mr. Smith:

This letter corrects our substantially equivalent letter of September 18, 2007.

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.

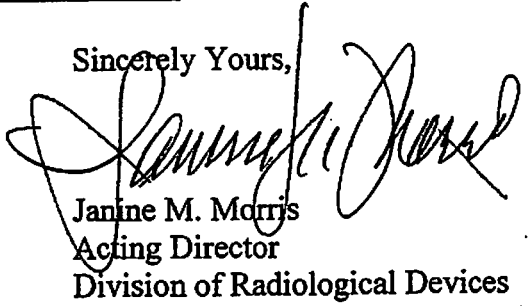
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's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



Janine M. Morris
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): K071546

Device Name: EOS

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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)

(Division Sign-Off)
Division of Reproductive, Abdominal and Radiological Devices
510(k) Number K071546