



Food and Drug Administration  
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EOS Imaging  
% John J. Smith, M.D., J.D  
Partner  
Hogan Lovells US LLP  
555 Thirteenth Street, NW  
WASHINGTON DC 20004

October 21, 2015

Re: K152788  
Trade/Device Name: EOS System  
Regulation Number: 21 CFR 892.1680  
Regulation Name: Stationary x-ray system  
Regulatory Class: II  
Product Code: KPR  
Dated: September 25, 2015  
Received: September 25, 2015

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 black ink that reads "Robert Ochs". The signature is written in a cursive style with a large, prominent "R" and "O".

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)

**K152788**

Device Name

EOS System

Indications for Use (Describe)

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.

The Micro Dose feature is indicated for imaging with a patient entrance dose of 10 to 90  $\mu$ Gy for assessing global skeletal deformities in follow-up pediatric examinations. Micro Dose is not indicated for focal skeletal abnormalities and/or other pediatric abnormalities. Micro Dose is not indicated for use in patients with a Body Mass Index over 30.

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.

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## 510(k) SUMMARY

### EOS imaging's EOS System

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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:** October 13, 2015

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

EOS System  
EOS imaging  
10 rue Mercoeur  
PARIS F-75011  
FRANCE

**Common or Usual Name:** Digital Radiography System

**Classification Name:** 21 CFR 892.1680; Stationary X-ray System  
Product Code KPR – System, X-Ray, Stationary

**Predicate Devices:** K142773 cleared on January 22, 2015  
Trade/Device Name: EOS System  
Regulation: 21 CFR 892.1680; Stationary X-Ray System  
Regulatory Class: II; Product Code: KPR, MQB

**Intended Use/ indication for use**

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.

The Micro Dose feature is indicated for imaging with a patient entrance dose of 10 to 90  $\mu$ Gy for assessing global skeletal deformities in follow-up pediatric examinations. Micro Dose is not indicated for focal skeletal abnormalities and/or other pediatric abnormalities. Micro Dose is not indicated for use in patients with a Body Mass Index over 30.

**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 by scanning the patient over the area of interest. An acquisition feature named Micro Dose allows image acquisition with a patient entrance dose of 10 to 90  $\mu$ Gy for assessing global skeletal deformities in follow-up pediatric exams. The diagnostic images are stored in a local 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.

## Performance Data

EOS is designed to conform to IEC 60601-1 and collateral standards. A CB (certification body) test certificate has been issued. Software verification and validation testing was also conducted. Additional performance and functional testing has confirmed the equivalent performance of the modified EOS compared to the cleared predicate EOS. This testing included bench testing to confirm appropriate dosing and image quality.

## Substantial Equivalence

The modified EOS has the same intended use and similar indications, principles of operation, and technological characteristics as the cleared predicate device.

	Modified EOS System (K152788)	Comparison with cleared Predicate EOS System (K142773)
Intended Use/ Indications for Use	Both devices have the same intended use.	
Technological Characteristics / Principles of Operation	The fundamental technological characteristics of the modified EOS are unchanged from the cleared EOS. The modified EOS contains the following minor modifications that have been implemented following the last clearance:	
<ul style="list-style-type: none"> <li>Hardware Modifications</li> </ul>	Component Supplier Changes	The change in suppliers has not resulted in any changes to the design or manufacturing specifications of the system. Performance and functional testing has confirmed non-regression.
	Modification to electrical components following obsolescence	Components have been replaced with iso-functional components.
	Mirror Sticker Accessory	New optional accessory kit
<ul style="list-style-type: none"> <li>Software Modifications</li> </ul>	Software modification related to a recall action.	The acquisition software has been modified in order to improve the detection of a dysfunction of the spectral filter and to prevent the use of the system after the alert message on spectral filtration appears.
	Optimization of default acquisition protocols	Performance testing has demonstrated that this modification allows reducing the entrance dose for the changed protocols, with maintaining equivalent or better image quality than the cleared EOS.
	Improvement of image processing.	The aim of this optimization is to increase the image contrast and dynamic during the image processing.
	Addition of a new features like Dose Structured Report and Reject and Repeat Analysis ("RRA")	New feature

## Conclusions

The minor differences in the modified EOS's technological characteristics do not raise any new questions of safety or effectiveness. Performance data demonstrates that the modified EOS is as safe and effective as the cleared predicate device. Thus, the modified EOS is substantially equivalent to its predicate device.