November 27, 2019

EOS Imaging
c/o Bernard Ismael
Quality and Regulatory Affairs Director
10 rue Mercoeur
Paris, 75011
FRANCE

Re: K192079
Trade/Device Name: EOSedge
Regulation Number: 21 CFR 892.1680
Regulation Name: Stationary X-Ray System
Regulatory Class: Class II
Product Code: KPR
Dated: July 31, 2019
Received: August 2, 2019

Dear Bernard Ismael:

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; 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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). 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 (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Thalia T. Mills, Ph.D.
Director
Division of Radiological Health
OHT7: Office of In Vitro Diagnostics
and Radiological Health
Office of Product Evaluation and Quality
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: 06/30/2020
See PRA Statement on last page

510(k) Number *(if known)*

K192079

Device Name

EOSedge™

Indications for Use *(Describe)*

EOSedge is intended for use in general radiographic exams and applications, excluding the evaluation of lung nodules and exams involving fluoroscopy, angiography, and mammography. EOSedge 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 assessing global skeletal deformities in follow-up pediatric exams.

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.

510(k) SUMMARY

EOS imaging's EOSedge System

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Contact Person: Bernard ISMAEL, Quality and Regulatory Affairs Director

Date Prepared: July 31, 2019

Name of Device:	EOSedge™
Common or Usual Name:	Digital Radiography System
Classification Name:	21 C.F.R §892.1680; Stationary X-ray System
Regulatory Class:	Class II
Product Code:	KPR – System, X-ray, Stationary
Predicate Device:	EOS imaging's EOS System (K152788)

Device Description

The EOSedge system is a digital radiography system comprised of an acquisition workstation, a gantry including an electrical cabinet housing the system power and communication controls, and an acquisition software to obtain diagnostic images. Two sets of detectors and X-ray tubes are positioned orthogonally to generate frontal and lateral images simultaneously by scanning the patient over the area of interest. If desired, the Micro Dose feature enables image acquisition for assessing global skeletal deformities in follow-up exams. The diagnostic images are stored in a local database and are displayed on a high-resolution medical-quality non-diagnostic monitor. The diagnostic image can be transmitted through a DICOM compatible digital network for printing and archiving.

Intended Use / Indications for Use

EOSedge is intended for use in general radiographic exams and applications, excluding the evaluation of lung nodules and exams involving fluoroscopy, angiography, and mammography. EOSedge 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 assessing global skeletal deformities in follow-up pediatric exams.

Performance Data

EOSedge is designed and has been certified to conform to IEC 60601-1 and collateral standards. Software verification and validation testing was also conducted. Additional performance and functional

testing have confirmed the equivalent performance of EOSedge compared to the cleared predicate EOS System. This included bench testing to confirm appropriate dosing and image quality. Bench performance testing were conducted based on FDA's *Guidance for the Submission of 510(k)'s for Solid-State X-ray Imaging Devices (September 1, 2016)*, to verify that EOSedge performs according to specifications and is as safe and effective as the predicate device.

Substantial Equivalence

EOSedge has the same intended use and similar indications, principles of operation, and technological characteristics as the cleared predicate device. EOSedge is an updated version of the cleared EOS System (K152788) with the main modification being a change in the type of detector used, namely, solid state photon counting detectors rather than gaseous detectors. Although the design of the equipment is being updated to accommodate the new detector, there are no major changes to the tube assembly and beam-limiting features. Both systems have two sets of detectors and X-ray tubes positioned orthogonally to generate frontal and lateral images simultaneously by scanning the patient over the area of interest. The two orthogonal acquisition chains consist of HV generators, X-ray tubes, collimators and detectors, positioned on C-shaped arms translating along a vertical axis. The software for the two systems are also fundamentally the same.

A substantial equivalence table summarizing the similarities and differences between EOSedge and its predicate device is provided below.

Table 1: EOS IMAGING'S EOSEDGE – SUBSTANTIAL EQUIVALENCE CHART

	EOS imaging's EOSedge	**EOS imaging's cleared EOS System (K152788)**
Intended Use	General X-ray imaging system	General X-ray imaging system
Indications for Use	EOSedge is intended for use in general radiographic exams and applications, excluding the evaluation of lung nodules and exams involving fluoroscopy, angiography, and mammography. EOSedge 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 assessing global skeletal deformities in follow-up pediatric examinations.	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 µGy 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.
Contraindications	EOSedge is not designed to perform fluoroscopy, angiography or mammography exams. The Micro Dose feature is not designed for morphological analysis of bone structures and lesions. The Micro Dose feature is not indicated: • for analysis of spine static in the	This system was not designed to perform mammograms, angiograms or fluoroscopy examinations. The Micro Dose functionality is not designed for morphological analysis of bone structures and lesions. It is not indicated for analysis of spine static in the presence of fusion material or for analysis of the bone-

	EOS imaging's EOSedge	**EOS imaging's cleared EOS System (K152788)**
	presence of fusion material or for analysis of the bone-implant interface • in the case of focal skeletal anomalies and/or other pediatric abnormalities • for use in patients with a Body Mass Index over 30	implant interface.
User Population	Trained medical personnel	Trained medical personnel
Technological Characteristics	Digital radiography system in which two sets of detectors and X-ray tubes are positioned orthogonally to generate frontal and lateral images simultaneously by scanning the patient over the area of interest. The 2 orthogonal acquisition chains consist of HV generators, X-ray tubes, collimators and detectors, positioned on C-shaped arms translating along a vertical axis.	Digital radiography system in which two sets of detectors and X-ray tubes are positioned orthogonally to generate frontal and lateral images simultaneously by scanning the patient over the area of interest. The 2 orthogonal acquisition chains consist of HV generators, X-ray tubes, collimators and detectors, positioned on C-shaped arms translating along a vertical axis.
Dimensions (l x w x h)	2.58 m x 2.58 m x 2.706 m (8.5 ft x 8.5 ft x 8.9 ft)	2 m x 2 m x 2.7 m (7.9 ft x 7.9 ft x 10.44 ft)
Weight	2 005 kg (4 420 lb)	1 623 kg (3579 lb)
Accessories	Laser safety barriers Motorized lifting platform Gantry console Laser positioning system Access and stabilization bars Bar code reader	Mechanical platform Laser positioning system Access and stabilization bars
Principles of Operation	Tube preheating Selection of the patient, the acquisition planes, and the anatomical area, as well as patient positioning Selection of either automatic mode or manual mode Selection of patient morphotype Image preview Display of the exposure area, configuration of the reference planes, and verification and validation of the acquisition parameters Image analysis and export of the exam	Tube preheating *Daily detector calibration* Selection of the patient, the acquisition planes, and the anatomical area, as well as patient positioning Selection of patient morphotype Image preview Display of the exposure area, configuration of the reference planes, and verification and validation of the acquisition parameters *Display of unprocessed images and reprocessing with various options* Image analysis and export of the exam *Printing*
Permanent minimum total filtration (Al equivalent)	1.7 mm Al at 75 kV Additional filtrations: o 0.1 mm copper thickness (used for images with or without Micro-Dose)	1.5 mm Al at 75 kV Additional filtrations: o 0.1 mm Cu copper thickness (used for images with or without Micro-Dose)

	EOS imaging's EOSedge	**EOS imaging's cleared EOS System (K152788)**
	o 0.5 mm copper thickness (used for the Scout View)	o 1 mm aluminum thickness (used for large patient with LF and power > 28 kW)
Detectors	Direct conversion device – solid state detector	Direct conversion device – gaseous detector
Pixel Depth	17 bits (> 131 000 grey levels)	16 bits (> 65 000 grey levels)
Pixel Size	100 µm	254 µm
Resolution	3.7 lp/mm	1.6 – 1.7 lp/mm
Typical Dynamic Range	> 100 dB	> 90 dB
Software Specifications	Patient information management Image acquisition Display images Send exam to the PACS Maintenance management Access management to the system System acquisition configuration.	Patient information management Image acquisition Display images Send exam to the PACS Maintenance management Access management to the system System acquisition configuration.
Focal Spot	Large focal spot: 0.6 x 1.3 at 120 kV – 100 mA	Large focal spot: 0.6 x 1.3 at 120 kV -100 mA Small focal spot: 0.4 x 0.7 at 120 kV - 50 mA Use of the two focal spot sizes enabled
Linear Scanning Speed (cm/s)	From 4.1 to 32.5	From 3.8 to 30.5
Average Acquisition Time	8 seconds for a spine and 15 seconds for an entire body	5 to 10 seconds for a spine and 20 seconds for an entire body

Conclusion

EOSedge has the same intended use and similar indications for use, technological characteristics, and principles of operation as its predicate device, the EOS System (K152788). The minor differences in indications for use and technology between EOSedge and its predicate device raise no new questions of safety or effectiveness. Performance data further demonstrates that EOSedge is as safe and effective as the cleared EOS System (K152788). Thus, EOSedge is substantially equivalent.