EOS imaging
℅ Mr. Bernard Ismael
Quality and Regulatory Affairs Director
10 rue Mercoeur
Paris, F-75011
FRANCE

September 16, 2020

Re: K202394
Trade/Device Name: EOSedge™
Regulation Number: 21 CFR 892.1680
Regulation Name: Stationary x-ray system
Regulatory Class: Class II
Product Code: KPR
Dated: August 19, 2020
Received: August 21, 2020

Dear Mr. 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,

For

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)*

K202394

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.

K202394 510(k) SUMMARY

EOS imaging's EOSedge System

EOS imaging
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Contact Person: Bernard ISMAEL, Quality and Regulatory Affairs Director

Date Prepared: August 19, 2020

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 EOSedge System (K192079)
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

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 identical 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 pediatric exams. The two sets of detectors and X-ray tubes are identical between the predicate device and the subject device. The image acquisition can be performed with a MANUAL mode or an AUTO mode of patient examination. To select the area of interest (acquisition area), a vertical collimation is set using green lasers and to correctly position the patient in the EOSedge, a centering system is used based on red lasers. 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.

The frontal and lateral detectors are identical. The technical specifications of the detectors are presented in the **Table 1** below:

Table 1: DETECTORS SPECIFICATIONS

Attribute		Technical Specifications
Quantity		2
Type		Hybrid CdTe-CMOS dual energy photons counting X-ray detector
Dimensions	Width	585 mm x 98 mm
	Thickness	131 mm
Weight		<10 kg
X-ray conversion material		CdTe
X-ray voltage range		< 160 kVp
Active area		514 mm x 6 mm
Pixel size		100 x 100 µm², elementary
Tile gap		<=100 µm
Overall fill factor		99.63%
Number of pixels/lines		5,139 pixels
Imaging speed		Up to 5,000 lines/s, in TDS mode
Counting output range (Pixel depth)		17 bits (TDS mode) (> 131 000 gray levels)
Nominal input voltage		12 VDC – 20 A
Temperature control		Internal check, Peltier + PWM Ventilator system checked
DQE type		RQA5 spectrum ~ 80%
MTF type		~70% @ 2lp / mm ~25% @ 5lp / mm

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.

All the testing standards used for bench testing of the EOSedge system are listed in **Table 2** below:

Table 2: BENCH TESTING STANDARDS USED FOR THE EOSEDGE SYSTEM

Standards N°.	Standards Title	Date
AAMI/ANSI ES60601-1 :2005/(R)2012 and A1:2012	Medical electrical equipment. Part 1: general requirements for basic safety and essential performance	2012
IEC 60601-1-2	Medical electrical equipment. Part 1-2: general requirements for safety; electromagnetic compatibility-requirements and tests.	2014
IEC 60601-1-3	Medical electrical equipment. Part 1-3: general requirements for safety; general requirements for radiation protection in diagnostic X-ray equipment.	2013
IEC 60601-1-6	Medical electrical equipment. Part 1-6: General requirements for basic safety and essential performance -Collateral standard: Usability	2013
IEC 60601-2-54	Medical electrical equipment. Part 2-54: Particular requirements for the basic safety and essential performance of X-ray equipment for radiography and radioscopy	2015
IEC 60825-1	Safety of laser products - Part 1: Equipment classification and requirements	2007
IEC 62220-1	Medical Electrical Equipment-Characteristics Of Digital X-Ray Imaging Devices, Part 1-1: Determination Of The Detective Quantum Efficiency, Detectors Used In Radiographic Imaging	2015

Substantial Equivalence

EOSedge has the same intended use, indications, principles of operation, and technological characteristics as the cleared predicate device. EOSedge is an updated version of the cleared EOSedge System (K192079) with the main modifications being optimization of some acquisition protocol parameters, improvement of image processing and change in system data processing.

A substantial equivalence table summarizing the similarities and differences between EOSedge and its predicate device is provided in **Table 3** below.

Table 3: EOS IMAGING'S EOSEDGE – SUBSTANTIAL EQUIVALENCE CHART

	EOS imaging's EOSedge	EOS imaging's cleared EOSedge System (K192079)
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.	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.
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.	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.

	EOS imaging's EOSedge	**EOS imaging's cleared EOSedge System (K192079)**
	The Micro Dose feature is not indicated: • for analysis of spine static in the 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	The Micro Dose feature is not indicated: • for analysis of spine static in the 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
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)	2.58 m x 2.58 m x 2.706 m (8.5 ft x 8.5 ft x 8.9 ft)
Weight	2 005 kg (4 420 lb)	2 005 kg (4 420 lb)
Accessories	Laser safety barriers Motorized lifting platform Platform console Laser positioning system Access and stabilization bars Bar code reader	Laser safety barriers Motorized lifting platform Platform console Laser positioning system Access and stabilization bars Bar code reader
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 Scout View 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 Dose Report Printing	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 Scout View 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
Permanent minimum total filtration (Al equivalent)	1.7 mm Al at 75 kV Additional filtrations: ○ 0.1 mm copper thickness (used for images with or without Micro-Dose) ○ 0.5 mm copper thickness (used for the Scout View)	1.7 mm Al at 75 kV Additional filtrations: ○ 0.1 mm copper thickness (used for images with or without Micro-Dose) ○ 0.5 mm copper thickness (used for the Scout View)
Detectors	Direct conversion device – solid state detector	Direct conversion device – solid state detector
Pixel Depth	17 bits (> 131 000 grey levels)	17 bits (> 131 000 grey levels)
Pixel Size	100 µm	100 µm
Resolution	3.7 lp/mm	3.7 lp/mm
Typical Dynamic Range	> 100 dB	> 100 dB

	EOS imaging's EOSedge	**EOS imaging's cleared EOSedge System (K192079)**
Values of the kV parameters	40 to 140 kV, bi-polar	40 to 140 kV, bi-polar
Values of the mA parameters	10 to 500 mA	10 to 500 mA
Software Specifications	Patient information management Image acquisition Display images Generation of dose report Send exam to the PACS or USB 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	0.6 x 1.3 at 120 kV – 100 mA	0.6 x 1.3 at 120 kV – 100 mA
Linear Scanning Speed (cm/s)	From 4.1 to 32.5	From 4.1 to 32.5
Average Acquisition Time	7 seconds for a spine and 13 seconds for an entire body	8 seconds for a spine and 15 seconds for an entire body
Laser Positioning System Maximum average radiant power/ wavelength Class according to IEC 60825-1	 0.136 mW / 520 nm (green) 0.130 mW / 635 nm (red) Class1	 0.136 mW / 520 nm (green) 0.130 mW / 635 nm (red) Class1

Conclusion

Modified EOSedge has the same intended use, indications for use, technological characteristics, and similar principles of operation as its predicate device, the cleared EOSedge System (K192079). The minor differences in principles of operation and software specifications between EOSedge and its predicate device raise no new questions of safety or effectiveness. Performance data further demonstrates that modified EOSedge is as safe and effective as the cleared EOSedge System (K192079). Thus, modified EOSedge is substantially equivalent.