August 6, 2024

EOS imaging
% Mathilde Masurel
Design Quality and Regulatory Affairs Specialist
10 rue Mercoeur
PARIS, 75011
FRANCE

Re: K233920
Trade/Device Name: EOSedge
Regulation Number: 21 CFR 892.1680
Regulation Name: Stationary x-ray system
Regulatory Class: Class II
Product Code: KPR
Dated: March 29, 2024
Received: July 8, 2024

Dear Mathilde Masurel:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

Lu Jiang

Lu Jiang, Ph.D.
Assistant Director
Diagnostic X-Ray Systems Team
DHT8B: Division of Radiological Imaging
Devices and Electronic Products
OHT8: Office of 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: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K233920

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 K233920

1 SUBMITTER

EOS imaging
10 rue Mercoeur
Paris, France 75011
Phone: +33 1 55 25 60 60
Fax: +33 1 55 25 60 61

Contact Person: Mathilde Masurel
Design Quality and Regulatory Affairs Specialist
EOS imaging
Contact Phone: +33 1 55 25 60 60

Date Summary Prepared: July 5, 2024

2 DEVICE

Trade Name:	EOSedge
Common or Usual Name:	Digital Radiography System
Classification Name:	Stationary X-ray System (21 C.F.R. § 892.1680)
Regulatory Class:	Class II
Product Code:	KPR

3 PREDICATE DEVICE

Trade Name:	EOSedge (K202394)
Common or Usual Name:	Digital Radiography System
Classification Name:	Stationary X-ray System (21 C.F.R. § 892.1680)
Regulatory Class:	Class II
Product Code:	KPR

4 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 pediatric 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.

5 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.

6 TECHNOLOGICAL COMPARISON TO PREDICATES

Modified EOSedge has the same intended use, indications, principles of operation, and technological characteristics as the cleared predicate device. Modified EOSedge is an updated version of the cleared EOSedge System (K202394) with the main modifications being the activation of the dual energy detection mode for detectors, already previously integrated into the product. The activation of this mode, induced the following modifications:

- Addition of dual energy acquisition protocols,
- New dual energy image process chain, and
- Detectors firmware modification to activate dual energy detection mode.

A substantial equivalence table summarizing similarities and differences between EOSedge and its predicate device is provided in **Table 1** below.

Table 1: Comparison for Substantial Equivalence

	EOS imaging's modified EOSedge system	EOS imaging's cleared EOSedge System (K202394)	Substantially Equivalent?
Intended Use	General X-ray imaging system	General X-ray imaging system	Yes - same
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.	Yes - same
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 presence of fusion material or for analysis of the bone-implant interface • in the case of focal skeletal anomalies and/or other pediatric abnormalities	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 presence of fusion material or for analysis of the bone-implant interface • in the case of focal skeletal anomalies and/or other pediatric abnormalities	Yes - same

	EOS imaging's modified EOSedge system	EOS imaging's cleared EOSedge System (K202394)	Substantially Equivalent?
	• for use in patients with a Body Mass Index over 30	• for use in patients with a Body Mass Index over 30	
User Population	Trained medical personnel	Trained medical personnel	Yes - same
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.	Yes - same
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)	Yes - same
Weight	2 005 kg (4 420 lb)	2 005 kg (4 420 lb)	Yes - same
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	Yes - same

	EOS imaging's modified EOSedge system	EOS imaging's cleared EOSedge System (K202394)	Substantially Equivalent?
Principles of Operation	Tube preheating Selection of the patient, the acquisition planes, and the anatomical area in single or dual energy, as well as patient positioning Selection of either AUTO (Automatic) mode or MANUAL (manual) mode Selection of patient morphotype Image preview (Scout View) Image acquisition i.e., display of the exposure area, configuration of the reference planes, and verification, validation of the acquisition parameters and launch of the image acquisition Image review i.e., use of display tools and 2D tools to add annotations Export of the exam to DICOM server(s) (PACS and/or sterEOS).	Tube preheating Selection of the patient, the acquisition planes, and the anatomical area in single energy, as well as patient positioning Selection of either AUTO (Automatic) mode or MANUAL (manual) mode Selection of patient morphotype Image preview (Scout View) Image acquisition i.e., display of the exposure area, configuration of the reference planes, and verification, validation of the acquisition parameters and launch of the image acquisition Image review i.e., use of display tools and 2D tools to add annotations Export of the exam to DICOM server(s) (PACS and/or sterEOS).	Yes - similar
Permanent minimum total filtration (Al equivalent)	1.7 mm Al at 75 kV Additional filtrations: • 0.1 mm copper thickness (used for single energy images with or without Micro-Dose) • 0.3 mm copper thickness (used for dual-energy images 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)	Yes – similar
Detectors	Direct conversion device – solid state detector	Direct conversion device – solid state detector	Yes – similar

	EOS imaging's modified EOSedge system	EOS imaging's cleared EOSedge System (K202394)	Substantially Equivalent?
	with single and dual energy detection mode activated	with single energy detection mode activated	
Pixel Depth	17 bits (> 131 000 gray levels)	17 bits (> 131 000 grey levels)	Yes - same
Pixel Size	100 µm	100 µm	Yes - same
Resolution	3.7 lp/mm	3.7 lp/mm	Yes - same
Typical Dynamic Range	> 100 dB	> 100 dB	Yes - same
Values of the kV parameters	40 to 140 kV, bi-polar	40 to 140 kV, bi-polar	Yes - same
Values of the mA parameters	3 to 400 mA	10 to 400 mA	Yes – similar
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 Generation of dose report Send exam to the PACS or USB Maintenance management Access management to the system System acquisition configuration	Yes - same
Focal Spot	0.6 x 1.3 at 120 kV – 100 mA	0.6 x 1.3 at 120 kV – 100 mA	Yes - same
Linear Scanning Speed (cm/s)	From 4.1 to 32.5	From 4.1 to 32.5	Yes - same

	EOS imaging's modified EOSedge system	EOS imaging's cleared EOSedge System (K202394)	Substantially Equivalent?
Average Acquisition Time	7 seconds for a spine and 13 seconds for an entire body	7 seconds for a spine and 13 seconds for an entire body	Yes - same
Laser Positioning System			
Maximum average radiant power/ wavelength	0.136 mW / 520 nm (green) 0.130 mW / 635 nm (red)	0.136 mW / 520 nm (green) 0.130 mW / 635 nm (red)	Yes - same
Class according to IEC 60825-1	Class 1	Class 1	Yes - same

7 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 EOSedge System (K202394). This included bench testing to confirm appropriate dosing and image quality. Bench performance testing was 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 related to the changes in this submission are listed in **Table 2** below:

Table 2: Bench Testing Standard Used for the EOSedge System

Standards N°.	Standards Title	Date
IEC 62304	Medical device software - Software life cycle processes	2015
IEC 62220-1-1	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

8 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 (K202394). 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 (K202394). Thus, the modified EOSedge is substantially equivalent.