March 28, 2024

GE OEC Medical Systems, Inc.
% Shawn Quigley
Regulatory Affairs Manager
384 Wright Brothers Drive
SALT LAKE CITY, UT 84116

Re: K233669
Trade/Device Name: OEC 3D
Regulation Number: 21 CFR 892.1650
Regulation Name: Image-Intensified Fluoroscopic X-Ray System
Regulatory Class: Class II
Product Code: OXO, JAA, OWB
Dated: February 27, 2024
Received: February 28, 2024

Dear Shawn Quigley:

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.

Submission Number *(if known)*

K233669

Device Name

OEC 3D

Indications for Use *(Describe)*

The OEC 3D mobile fluoroscopy system is designed to provide fluoroscopic and digital spot images of adult and pediatric populations during diagnostic, interventional, and surgical procedures. Examples of a clinical application may include: orthopedic, gastrointestinal,endoscopic, urologic, neurologic, vascular, cardiac, critical care, and emergency procedures.

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

This 510(k) Summary of Safety and Effectiveness information is submitted in accordance with the requirement of 21 CFR Part 807.87(h).

In accordance with 21 CFR 807.92 the following summary of information is provided:

Date: March 27, 2024

Submitter:
GE OEC Medical Systems, Inc (GE Healthcare)
384 Wright Brothers Drive
Salt Lake City, Utah 84116

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PRODUCT IDENTIFICATION

Device Trade Name: OEC 3D

Regulation Name: Image-intensified Fluoroscopic x-ray system
Classification Panel: Radiology
Regulation: 21CFR 892.1650
Classification: Class II
Product Code: OXO
Subsequent Product Codes JAA, OWB
Manufacturer:
GE OEC Medical Systems, Inc (GE HealthCare)
384 Wright Brothers Drive.
Salt Lake City, Utah 84116

Manufacturing Location:
GE OEC Medical Systems, Inc (GE HealthCare)
384 Wright Brothers Drive.
Salt Lake City, Utah 84116

Predicate Device:

Device Name:	OEC 3D
510(k) number:	K203346
Manufacturer:	GE OEC Medical Systems, Inc

Regulation Name:	Image-intensified Fluoroscopic x-ray system
Regulation:	21CFR 892.1650
Classification:	Class II
Product Code:	OXO
Subsequent Product Code:	OWB, JAA

Device Description:

The OEC 3D is a mobile fluoroscopic C-Arm imaging system used to assist trained surgeons and other qualified physicians. The system is used to provide fluoroscopic X-ray images and volumetric reconstructions during diagnostic, interventional, and surgical procedures. These images help the physician visualize the patient's anatomy and interventional tools. This visualization helps to localize clinical regions of interest and pathology. The images provide real-time visualization and records of pre-procedure anatomy, in vivo-clinical activity and post-procedure outcomes.

The system is composed of two major components, a C-Arm and a tethered Workstation.

The C-Arm is a stable mobile platform capable of performing linear motions (vertical, horizontal) and rotational motions (orbital, lateral) that allow the user to position the X-ray image chain at various angles and distances with respect to the patient anatomy to be imaged. The C-Arm is comprised of the high voltage generator, software, X-ray control, and a "C" shaped image gantry, which supports an X-ray tube and a Flat Panel Detector. Its functionality is controlled by software on the Workstation and on the OEC Touch, a digital flat panel controller mounted on the cross-arm.

The workstation is a stable mobile platform with an articulating arm supporting a color image high resolution LCD display monitor. It also includes image processing equipment/software, recording devices, data input/output devices and power control systems. The Workstation is the primary user interface to the system and can be located at a convenient location in the room independent of where the C-Arm is located.

On the C-Arm, the generator remains unchanged from the predicate device OEC 3D. This is also true for the 31 cm x 31 cm image receptor, consisting of a Thallium-doped Cesium Iodide [CsI (Tl)] solid state flat panel X-ray detector with Complementary Metal Oxide Semiconductor (CMOS) light imager. The X-ray tube housing and insert remains the same as on the predicate OEC 3D (K203346).

C-Arm functionality is managed by a digital flat tablet control panel mounted on the C-arm base. Motion is controlled by a joystick.

On the workstation, the main hardware includes a computer with integrated wireless capability and a dedicated computer for 3D reconstruction located within the storage bay. The OEC 3D employs the same software architecture and platform design that fully supports the flat panel detector as the predicate OEC 3D and complies with IEC 60601-1.

The purpose of this Premarket Notification is to demonstrate that the subject device, OEC 3D, is a modification of and is substantially equivalent to the predicate device OEC 3D (K203346).

Proposed Device Modification:

The device name for the subject device remains the same as the cleared predicate: OEC 3D. (K203346). The proposed modifications are being made to GE HealthCare's cleared predicate OEC 3D system (K203346).

The primary modifications to the cleared OEC 3D device are as follows:

1. 3D Spine Centerline Tool with Manual Labeling of the Vertebrae
2. 3D Screw Evaluation Tool
3. Augmented Fluoroscopy

Indications for Use:

The OEC 3D mobile fluoroscopy system is designed to provide fluoroscopic and digital spot images of adult and pediatric populations during diagnostic, interventional, and surgical procedures. Examples of a clinical application may include: orthopedic, gastrointestinal, endoscopic, urologic, neurologic, vascular, cardiac, critical care and emergency procedures.

The intended use and indications for use are unchanged from the predicate device.

Technology:

The indications for use are identical and technology is similar to the predicate device. X-ray generation and control used with the subject device OEC 3D is identical to the technology used with the predicate device OEC 3D. The subject OEC 3D device employs the same fundamental technology as that of the predicate device. The image chain including the X-ray tube, high voltage generator, collimator, X-ray filters, and detectors, remains unchanged from the predicate, OEC 3D.

The system continues to meet all applicable IEC 60601-1 series of standards, NEMA XR-27, and applicable parts of 21CFR Subchapter J. The new performance claims did not require clinical data in order to establish safety or efficacy.

The OEC 3D device was built upon the existing modular and extensible software architecture, following the same design control process and software development lifecycle process that is compliant to IEC 62304 used in the predicate OEC 3D.

The changes described above do not change the control mechanism, operating principle, energy type, or the scientific technology of the predicate devices.

Table 1: Subject and Predicate Device Comparison

	Subject Device **Modified OEC 3D**	**Predicate Device** **OEC 3D (K203346)**	**Discussion of Differences**
X-Ray Tube Assembly	➢ Type: rotating anode ➢ Focal spot: 0.3 mm & 0.6 mm ➢ Anode heat capacity: 300,000 HU ➢ Anode cooling rate: 85,000 HU/min ➢ Housing cooling rate: 68,000 HU/min ➢ Housing heat capacity: 1,800,000 HU	➢ Type: rotating anode ➢ Focal spot: 0.3 mm & 0.6 mm ➢ Anode heat capacity: 300,000 HU ➢ Anode cooling rate: 85,000 HU/min ➢ Housing cooling rate: 68,000 HU/min ➢ Housing heat capacity: 1,800,000 HU	Identical
X-ray Generator	➢ High frequency, DC ➢ 15 kW ➢ Peak tube potential: 40-120 kVp ➢ Fluoroscopy: 0.2-10.0 mA ➢ High level fluoro: 0.2-20.0 mA ➢ Pulsed fluoro: 4, 8, 15, 30 pulses/sec	➢ High frequency, DC ➢ 15 kW ➢ Peak tube potential: 40-120 kVp ➢ Fluoroscopy: 0.2-10.0 mA ➢ High level fluoro: 0.2-20.0 mA ➢ Pulsed fluoro: 4, 8, 15, 30 pulses/sec	Identical
Collimator	➢ Iris ➢ Secondary ➢ Tungsten dual leaf	➢ Iris ➢ Secondary ➢ Tungsten dual leaf	Identical
X-ray Control Modes	➢ Auto mode ➢ Manual mode	➢ Auto mode ➢ Manual mode	Identical

	Subject Device **Modified OEC 3D**	**Predicate Device** **OEC 3D (K203346)**	**Discussion of Differences**
	➢ (Normal fluoro, High level fluoro, Low dose fluoro)	➢ (Normal fluoro, High level fluoro, Low dose fluoro)	
Standards Compliance	➢ ANSI/AAMI ES60601-1 ➢ IEC 60601-1-2 ➢ IEC 60601-1-3 ➢ IEC 60601-2-43 ➢ IEC 60601-2-54 ➢ IEC 60601-1-6 ➢ IEC 60825-1 ➢ IEC 62304 ➢ NEMA DICOM PS 3.1-3.20 ➢ NEMA XR-27	➢ ANSI/AAMI ES60601-1 ➢ IEC 60601-1-2 ➢ IEC 60601-1-3 ➢ IEC 60601-2-43 ➢ IEC 60601-2-54 ➢ IEC 60601-1-6 ➢ IEC 60825-1 ➢ IEC 62304 ➢ NEMA DICOM PS 3.1-3.20 ➢ NEMA XR-27	Identical
Imaging Modes	➢ Continuous fluoroscopy o Normal dose o High level dose o Low dose ➢ Pulsed fluoroscopy o Normal dose o High level dose o Low dose ➢ Digital spot ➢ Digital cine pulse o Normal dose o Low dose ➢ Subtraction o Normal dose o Low dose ➢ Roadmap o Normal dose	➢ Continuous fluoroscopy o Normal dose o High level dose o Low dose ➢ Pulsed fluoroscopy o Normal dose o High level dose o Low dose ➢ Digital spot ➢ Digital cine pulse o Normal dose o Low dose ➢ Subtraction o Normal dose o Low dose ➢ Roadmap o Normal dose	Identical

	Subject Device **Modified OEC 3D**	**Predicate Device** **OEC 3D (K203346)**	**Discussion of Differences**
	○ Low dose	○ Low dose	
3D Imaging Modes	➢ HD+ (30s, 400 images) ➢ HD+ Low dose (30s, 400 images) ➢ HD (30s, 400 images) ➢ HD Low dose (30s, 400 images) ➢ SD (30s, 200 images) ➢ SD Low dose (30s, 200 images)	➢ HD+ (30s, 400 images) ➢ HD+ Low dose (30s, 400 images) ➢ HD (30s, 400 images) ➢ HD Low dose (30s, 400 images) ➢ SD (30s, 200 images) ➢ SD Low dose (30s, 200 images)	Identical
3D Imaging Features	➢ Coronal views ➢ Sagittal views ➢ Axial views ➢ Oblique views (Multi-Planar Reformat) ➢ 3D volume render view (VR) ➢ Maximum Intensity Projection view ➢ Window/Level (brightness/contrast) ➢ Image rotation ➢ Image zoom ➢ Metal artifact reduction ➢ 3D Spine Centerline Tool with Labeling ➢ 3D Spine Screw Evaluation Tool ➢ Augmented Fluoroscopy	➢ Coronal views ➢ Sagittal views ➢ Axial views ➢ Oblique views (Multi-Planar Reformat) ➢ 3D volume render view (VR) ➢ Maximum Intensity Projection view ➢ Window/Level (brightness/contrast) ➢ Image rotation ➢ Image zoom ➢ Metal artifact reduction	Substantially Equivalent 3D Spine Centerline Tool with labeling identifies vertebrae levels in a 3D volume with centroids and facilitates oblique viewing along the spine centerline defined by the centroids. The tool gives the user the option to label vertebrae levels manually. 3D Spine Screw Evaluation Tool is a method to select an oblique view for reviewing screw placement. Augmented fluoroscopy is a

	Subject Device **Modified OEC 3D**	**Predicate Device** **OEC 3D (K203346)**	**Discussion of Differences**
			method to overlay a 3D point of interest in an imaging volume on live fluoroscopy (2D X-ray). The new 3D imaging features do not raise new questions for safety and effectiveness.

Determination of Substantial Equivalence:

GE HealthCare believes the modified OEC 3D is of comparable type and substantially equivalent to the cleared predicate OEC 3D.

Non-Clinical Performance Testing

The verification and validation testing have been successfully completed as required by design control procedures under GE HealthCare's quality system. The system has been tested and is compliant with the IEC 60601-1, including IEC 60601-1-2, 60601-1-3, 60601-2-43, and 60601-2-54. All applicable 21CFR Subchapter J performance standards are met., 1020.30 Diagnostic X-Ray Systems and their major components, 1020.32 Fluoroscopic equipment, 1040.10 Laser products.

The OEC 3D system was developed under the GE OEC Medical Systems Quality Management System, including design controls, risk management and software development life cycle processes. The following quality assurance measures were applied to the development of the system:

- Risk Analysis
- Required Reviews
- Design Reviews
- Testing on Unit Level (Module verification)
- Integration testing (System verification)
- Performance testing (Verification)
- Safety testing (Verification)
- Simulated use testing (Validation)

The substantial equivalence was also based on a basic software documentation level.

Additional Non-Clinical Performance Testing

The 3D Centerline Tool with Labeling and the 3D Screw Evaluation Tool performance were evaluated on cadaveric volume datasets of the spine representing different imaging conditions.

The Augmented Fluoroscopy feature is a method to overlay a 3D point of interest in an imaging volume on live fluoroscopy (2D X-ray). This method projects a 3D point with some error compared to its actual position in the associated fluoroscopic image. Performance testing was done to quantify this error for accuracy using a rigid phantom.

Clinical Testing

The modified OEC 3D device is substantially equivalent to the cleared predicate for OEC 3D. The indication for use is identical and has equivalent/identical technological characteristics. This type of notification supports using scientific, established, engineering-based performance testing. The system has been fully tested using engineering bench testing. Clinical data is not required to demonstrate substantial equivalence for the modified OEC 3D device compared to the cleared predicate.

Substantial Equivalence Conclusion:

The OEC 3D device follows the same design control process and software development lifecycle processes as the predicate OEC 3D (K203346).

The differences discussed in this section do not introduce any adverse effects nor raise new questions of safety and effectiveness. Based on the successful verification and validation testing, additional performance bench testing, conformance to standards, and development under GE OEC Medical System's Quality Management System, we believe that the modified OEC 3D device is substantially equivalent to the cleared predicate device OEC 3D (K203346) and therefore, is safe and effective for its intended use.