GE OEC Medical Systems, Inc.
℅ Rachel Schandel
Regulatory Affairs Leader
384 N Wright Brothers Drive
SALT LAKE CITY UT 84116

March 5, 2021

Re: K203346
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, OWB, JAA
Dated: February 5, 2021
Received: February 8, 2021

Dear Rachel Schandel:

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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*

K203346

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: February XX , 2020

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

Primary Contact:
Rachel Schandel
Regulatory Affairs Leader
Tel: +1-385-237-7519
e-mail: rachel.schandel@ge.com

Secondary Contacts:
Philip Malca
Regulatory Affairs Director
General Electric Company
Tel: +33 646-373-852
e-mail: philip.malca@ge.com

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 Codes: OXO, OWB, JAA
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 Elite
510(k) number:	K192819
Manufacturer:	GE OEC Medical Systems, Inc
Regulation Name:	Image-intensified Fluoroscopic x-ray system
Regulation:	21CFR 892.1650
Classification:	Class II
Product Code:	OWB, OXO, JAA

Primary Reference Device:

Device Name:	Cios Spin (VA30)
510(k) number:	K181550
Manufacturer:	Siemens Medical Solutions USA, Inc.
Regulation Name:	Image-intensified Fluoroscopic x-ray system
Regulation:	21CFR 892.1650
Classification:	Class II
Product Code:	OWB, OXO, JAA

Secondary Reference Device:

Device Name:	INNOVA IGS 5
510(k) number:	K181403
Manufacturer:	GE Medical Systems SCS
Regulation Name:	Image-intensified Fluoroscopic x-ray system
Regulation:	21CFR 892.1650
Classification:	Class II
Product Code:	OWB, JAA, IZI and OXO

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 primary physical components. The first is referred to as the "C-Arm" because of its "C" shaped image gantry; the second is referred to as the "Workstation", and this is the primary user interface for the user to interact with the system. The C-arm has an interface tablet allowing a technician to interact with the system.

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,

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.

On the C-Arm, the generator remains unchanged from the OEC Elite. 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 Elite (K192819).

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 OEC Elite and complies with IEC 60601-1. The OEC 3D includes the existing 2D imaging functionalities available on the OEC Elite including imaging and post processing applications.

The change that triggered this submission for the subject device compared to the predicate, OEC Elite, is the introduction of the new 3D functionality. However, the new 3D function is substantially equivalent to the Siemens Inc. Cios Spin (K181550) and the 3D algorithm is identical to the Medical Systems INNOVA IGS 5 (K181403). Additionally, software and hardware are comparable to the OEC Elite (K192819).

This premarket notification is being submitted as a Traditional 510(k) to request clearance for the Subject Device the OEC 3D device. The subject device OEC 3D is substantially equivalent to the GE Healthcare predicate device OEC Elite (K192819) and the reference devices: Cios Spin (K181550) as well as INNOVA IGS 5(K181403) , they are within the same classification and regulation with these devices.

Proposed Device Modification:

The proposed OEC 3D device is a modification of GE's own predicate OEC Elite system (K192819). Its built upon the existing technologies of the predicate device "OEC Elite" (K192819).

The primary modifications for the OEC 3D as compared to OEC Elite are summarized below:

1. Composite isocentric C gantry
2. Dedicated 3D reconstruction computer
3. Live view camera embedded in the detector housing
4. Recirculating oil cooler on the X-ray tube

The wheels and wheel brakes, cable wraps, working surface, ergonomic handles, aesthetic open frame, LCD monitor, articulating arm and latch system remain unchanged from the OEC Elite.

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.

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 Elite. 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 Elite. The 3D functionality is similar to the reference device Cios Spin and INNOVA IGS 5. Table 1 provides predicate and reference device comparison.

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 IEC62304 used in the predicate OEC Elite.

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

Table 1: Predicate and Reference Device Comparison

Device Name and Manufacturer	**510(k) Number**	**Clearance Date**	**Comparable Properties**
Predicate Device: OEC Elite GE OEC Medical Systems, Inc Product Codes: OWB, OXO, JAA	K192819	11/08/2019	- Indications for Use - X-ray tube assembly - X-ray generator - Collimator - Image receptor - X-ray control modes - X-ray initiation and termination - Imaging modes - Dose area product - Imaging features - Image noise reduction - Power requirements - C-arm dimensions - C-arm positioning - Motorization - Workstation dimensions - Display articulation - Primary monitor - Control panel - Software platform - Computing hardware platform - Image management - Image storage - Data transfer - Alignment Aid - Standards compliance
Primary Reference Device: Cios Spin Siemens Medical Solutions USA, Inc. Product Codes: OWB, OXO, JAA	K181550	10/30/2018	- Isocentric C-arm design - 3D imaging modes - 3D imaging features - Navigation interface

Device Name and Manufacturer	510(k) Number	Clearance Date	Comparable Properties
Secondary Reference Device: INNOVA IGS 5 GE Medical Systems SCS 283 Rue De La Miniere, 78530 BUC, France Product Codes: JAA, IZI and OXO	K181403	11/02/2018	- 3D Algorithm

Determination of Substantial Equivalence:

The main change in the proposed device is the introduction of the 3D functionality.

The table below summarizes the substantive feature/technological differences between the predicate device and the proposed device:

Key Difference Category	Subject Device: OEC 3D	Predicate Device: OEC Elite (K192819)	Reference Device: Cios Spin (K181550)	Comparison Results
X-ray Tube Assembly	X-ray tube assembly with housing, tube insert, and recirculating oil cooling unit.	X-ray tube assembly with housing and tube insert.	NA	Improved cooling rate and capacity does not raise any new issues of safety and effectiveness.
Power Requirements	115-120V 20A power for additional computing hardware.	100-120V 15A power.	NA	Change in power consumption does not raise any new issues of safety and effectiveness.
C-arm Dimensions	Isocentric gantry design changes overall dimensions and weight.	Offset gantry design.	NA	C-arm dimensions do not raise any new issues of safety and effectiveness.
C-arm Positioning	Increased orbital range for 3D scanning.	Orbital range commensurate with 2D imaging.	NA	C-arm positioning does not raise any new issues of safety and effectiveness.
Workstation Dimensions	Workstation weight increased due to additional computer and support hardware.	Base configuration workstation weight.	NA	Workstation weight does not raise any new issues of safety and effectiveness.
Computing Hardware Platform	Two computers, one computer for imaging functions and features and second computer for	One computer for imaging functions and features.	NA	Additional computer does not raise any new issues of safety and effectiveness.

Key Difference Category	**Subject Device: OEC 3D**	**Predicate Device: OEC Elite (K192819)**	**Reference Device: Cios Spin (K181550)**	**Comparison Results**
	3D feature.			
Alignment Aid	Laser aimer and preview camera.	Laser aimer.	NA	Addition of preview camera does not raise any new issues of safety and effectiveness.
C-arm Design	Isocentric gantry capable of rotating 200 degrees.	NA	Isocentric gantry capable of rotating 196 degrees.	Gantry design change does not raise any new issues of safety and effectiveness.
3D Imaging Modes	Six modes with 200-400 images per scan.	NA	Four modes with 100-400 images per scan.	Imaging modes are similar and do not raise any new issues of safety and effectiveness.
3D Imaging Features	Comprehensive set of adjustments and viewing options for visualizing 3D reconstructions, plus a maximum intensity projection (MIP) view.	NA	Comprehensive set of adjustments and viewing options for visualizing 3D reconstructions.	Imaging features are similar and do not raise any new issues of safety and effectiveness.

Non-Clinical Performance Testing

The OEC 3D device has successfully completed verification and validation testing per GE Healthcare quality system as well engineering bench testing in support of this submission. 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
- Integration testing (System verification)
- Performance testing (Verification)
- Safety testing (Verification)
- Simulated use testing (Validation)

The substantial equivalence was also based on software documentation for a "**Moderate**" level of concern device.

Clinical Testing

The subject OEC 3D device is substantially equivalent to the predicate and reference devices. 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 can be fully tested/evaluated using engineering bench testing and clinical data is not required to demonstrate substantial equivalence.

Summary:

OEC 3D uses identical imaging, identical Indications for Use, and has equivalent/identical technological characteristics to the predicates. This type of device supports using scientific, established, engineering-based performance testing. The system can be fully tested/evaluated using engineering bench testing and clinical data is not required to demonstrate substantial equivalence. Results of all conducted testing assessments were found acceptable and do not raise any new issues of safety or effectiveness.

Substantial Equivalence Conclusion:

The OEC 3D device was built upon the existing modular and extensible predicate OEC Elite device (K192819), following the same design control process and software development lifecycle processes.

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 engineering bench testing, conformance to standards, and development under GE OEC Medical System's Quality Management System, we believe that the subject OEC 3D device is of comparable type and substantially equivalent to the predicate device OEC Elite (K192819) with support from the reference devices Siemens Cios Spin device (K181550) and INNOVA IGS 5 (K181403), and therefore is safe and effective for its intended use.