DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
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August 10, 2017

GE OEC Medical Systems, Inc.
Rachel Schandel
Regulatory Affairs Leader
384 Wright Brothers Drive
Salt Lake City, Utah 84116

Re: K171565
Trade/Device Name: OEC Elite
Regulation Number: 21 CFR 892.1650
Regulation Name: Image-intensified fluoroscopic x-ray system
Regulatory Class: Class II
Product Code: OWB, JAA, OXO
Dated: July 26, 2017
Received: July 27, 2017

Dear Ms. 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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely,

Michael D. O'Hara For

Robert A. Ochs, Ph.D.
Director
Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*

K171565

Device Name
OEC Elite

Indications for Use *(Describe)*

The OEC Elite mobile fluoroscopy system is designed to provide fluoroscopic and digital spot images of adult and pediatric patient populations during diagnostic, interventional, and surgical procedures. Examples of a clinical application may include orthopedic, gastrointestinal, endoscopic, urologic, neurologic, vascular, 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).

Date: May 26th, 2017

Submitter:
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PRODUCT IDENTIFICATION

Device Trade Name: **OEC Elite**

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

Manufacturing Location(s): 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:	K170752
Manufacturer:	GE OEC Medical Systems, Inc (same as proposed device)
Regulation Name:	Image-intensified Fluoroscopic x-ray system
Regulation:	21CFR 892.1650
Classification:	Class II
Product Code:	OWB, JAA, OXO

Marketed Device:

OEC Elite with Vascular option is a Mobile Fluoroscopic C-arm Imaging System with modification to the predicate device OEC Elite (K170752) to offer the users the vascular features. It is of comparable type and substantially equivalent to the predicate device OEC Elite. This 510(k) submission for the OEC Elite system with vascular option includes the same intended use and substantially equivalent indications for use as its predicate device. The existing indications for use of OEC Elite are expanded to include the vascular capability which is one of the current clinical uses of mobile c-arm systems that are well established in the medical community.

The system is labeled as the OEC Elite.

Device Description:

The OEC Elite 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 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", which is the primary interface for the user 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, wig-wag) 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 mechanically balanced allowing for ease of movement and capable of being "locked" in place using a manually activated lock. 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 or Image Intensifier, depending on the choice of detector configuration desired.

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 primary purpose of the mobile fluoroscopy system is to provide fluoroscopic images of the patient during diagnostic, interventional, and surgical procedures such as orthopedic, gastrointestinal, endoscopic, urologic, neurologic, vascular, critical care and emergency procedures.

The primary technology change for the subject device compared to the unmodified predicate, OEC Elite, is the introduction of the vascular capabilities.

Intended Use

The OEC Elite Mobile C-arm is intended to provide fluoroscopic and digital spot images of the patient anatomy, interventional tools/devices, and contrast agents during diagnostic, interventional, and surgical procedures.

Indications for Use:

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

Technology:

The OEC Elite with Vascular option employs the same fundamental scientific technology as that of the predicate device OEC Elite (K170752).

The image chain including the X-Ray source and generator remain unchanged from that of the predicate OEC Elite. The primary change was in the software to implement the vascular features such as Subtraction, Roadmapping, and Digital cine pulse to help perform vascular procedures with the easiest workflow and least intervention by the user. A suite of supporting features such as Peak opacification, Cine Recording/playback, Cine Automatic image playback, Cine Frame-by-frame review, Re-registration, Variable landmarking, and Mask save/recall, were added to further enhance the vascular workflows. Additionally a new vascular profile was developed to optimize the visualization of positive contrast agent-filled vessels, catheters, stents, and other tools in vascular procedures performed in thick anatomy, while a Bolus Chase profile was created to optimize the visualization of the run-off procedures and interventional procedures using small guidewires.

The modifications however, were built upon the existing robust and extensible software architecture, following the same design control process and software development lifecycle process that is compliant to IEC60324. The changes described above do not change the control mechanism, operating principle, energy type, or intended use from the predicate device.

Determination of Substantial Equivalence:

The main change in the proposed device is the introduction of the vascular feature. The table below summarizes the substantive feature/technological differences between the predicate device and the proposed device:

	Predicate Device OEC Elite (K170752)	Proposed Device OEC Elite with Vascular Option
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	➢ 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** ➢ **Roadmap** o **Normal dose** o **Low dose** ➢ **Subtraction** o **Normal dose** o **Low dose**
Imaging Features	➢ Auto X-Ray technique control ➢ Noise and motion reduction ➢ Auto/Manual Brightness and Contrast Control ➢ Negate ➢ Swap and auto-swap ➢ Save and auto-save ➢ Last image hold	➢ Auto X-Ray technique control ➢ Noise and motion reduction ➢ Auto/Manual Brightness and Contrast Control ➢ Negate ➢ Swap and auto-swap ➢ Save and auto-save ➢ Last image hold

	Predicate Device OEC Elite (K170752)	Proposed Device OEC Elite with Vascular Option
	➢ Edge enhancement ➢ Zoom & Roam ➢ Image rotation ➢ Image flip/ invert ➢ Manual/Auto Smart Metal ➢ AutoTrak ➢ Window/Level ➢ Patient Annotation ➢ Markers ➢ Measurement Functions	➢ Edge enhancement ➢ Zoom & Roam ➢ Image rotation ➢ Image flip/ invert ➢ Manual/Auto Smart Metal ➢ AutoTrak ➢ Window/Level ➢ Patient Annotation ➢ Markers ➢ Measurement Functions ➢ **Peak opacification** ➢ **Cine Recording/playback** ➢ **Cine Automatic image playback** ➢ **Cine Frame-by-frame review** ➢ **Re-registration** ➢ **Variable landmarking** ➢ **Mask save/recall**

GE Healthcare believes the OEC Elite with the Vascular option is of comparable type and substantially equivalent to our currently marketed system OEC Elite.

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

Summary of Additional Testing

In addition to the verification and validation testing successfully completed as required by GE OEC Medical System's Quality Management System, additional engineering (non-Clinical) testing was performed to provide the requisite data to substantiate performance claims, the revised indications, and ultimately substantial equivalence.

Non-Clinical Testing

Verification and validation, including hazard mitigation has been executed with results demonstrating the OEC Elite mobile fluoroscopy system met design input and user needs.

The system has been tested and is compliant with the IEC 60601-1 Ed. 3 series, including IEC60601-2-54 and IEC 60601-2-43. All applicable 21CFR Subchapter J performance standards are met. The OEC Elite 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 (Sub System verification)
- Integration testing (System verification)
- Performance testing (Verification)
- Safety testing (Verification)
- Simulated use testing (Validation)

Additional engineering bench testing was performed including demonstration of system performance; and an imaging performance evaluation using anthropomorphic phantoms. All the image quality/performance testing identified for fluoroscopy found in FDA's "Information for Industry: X-ray Imaging Devices- Laboratory Image Quality and Dose Assessment, Tests and Standards" was performed with acceptable results.

The OEC Elite with Vascular option was also evaluated for its performance per the FDA "Guidance for the Submission of 510(k)'s for Solid State X-ray Imaging Devices" (SSXI). It was determined the modified system continues to comply to this guidance. The evaluation includes but not limited to the following performance metrics identified in the SSXI guidance, showing identical performance of the subject device to the predicate device OEC Elite:

- DQE
- Dynamic Range
- Spatial Resolution (MTF, Limiting Resolution)
- Temporal Resolution
- Contrast Resolution
- Beam Alignment
- Dose Rate
- Stability of the device characteristics over time
- brightness uniformity
- Fluoroscopy Frame Rate
- Reuse Rate

Clinical Testing

Because OEC Elite with the vascular option does not change the system's intended use and represents equivalent technological characteristics, this type of change supports using scientific, established/standardized, engineering/physics-based performance testing, without inclusion of clinical images. Therefore, for OEC Elite with Vascular option configurations, clinical images are not required to demonstrate the substantial equivalence to the predicate device.

Substantial Equivalence Conclusion:

The differences discussed in this submission 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 OEC Elite is of comparable type and substantially equivalent to the predicate device OEC Elite (K170752) , and therefore is safe and effective for its intended use.