November 8, 2019

GE OEC Medical Systems, Inc.
% Kenny M. Bello
Regulatory Affairs Leader
384 N Wright Brothers Drive
SALT LAKE CITY UT 84116

Re: K192819
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: September 30, 2019
Received: October 1, 2019

Dear Kenny Bello:

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,

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 below.

510(k) Number *(if known)*
K192819

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, 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: September 27, 2019

Submitter:
GE OEC Medical Systems, Inc (GE Healthcare)
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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
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:	K172550
Manufacturer:	GE OEC Medical Systems, Inc
Regulation Name:	Image-intensified Fluoroscopic x-ray system
Regulation:	21CFR 892.1650
Classification:	Class II
Product Code:	OWB, JAA, OXO

Reference Device:

Device Name:	OEC Elite
510(k) number:	K171565
Manufacturer:	GE OEC Medical Systems, Inc
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 Enhanced Noise Reduction and associated claims, is a Mobile Fluoroscopic C-arm Imaging System built upon the existing technologies of the currently marketed predicate device, OEC Elite (K172550). It is of comparable type and substantially equivalent to the predicate device OEC Elite. In addition, the system has the same Intended Use and Indication for Use as the predicate device. 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 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.

GE is submitting this pre-market notification for proposed labeling changes (quantitative performance claims) related to a previously-released feature, Enhanced Noise Reduction.

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, cardiac, critical care, and emergency procedures.

Technology

In addition to the performance claims for the Enhanced Noise Reduction feature, the proposed device includes the accumulated changes to the predicate and reference devices.

The OEC Elite with Enhanced Noise Reduction and associated claims employs the same fundamental technology as that of the predicate and reference devices. 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 system continues to meet all applicable IEC 60601-1 series of standards, NEMA XR-27, and applicable parts of 21CFR Subchapter J. None of the accumulated changes affect the imaging characteristics and performance associated with FDA's SSXI Guidance. Incorporation of the wireless footswitch followed FDA's wireless guidance. The new performance claims and the accumulated changes did not require clinical data in order to establish safety or efficacy.

In order for FDA review of the proposed quantitative claims, the OEC Elite's performance with the Enhanced Noise Reduction feature has been scientifically tested and substantiated and included in this submission.

Enhanced Noise Reduction is a user-selectable, augmented image processing pathway available for Cardiac and Vascular acquisition profiles. Enhanced Noise Reduction reduces image noise in a manner characteristic of the reduction in noise resulting from an increase in photon flux. It is designed to maintain both spatial and temporal resolution. Use of Enhanced Noise Reduction does not change the tube output (dose).

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

	Predicate Device: OEC Elite K172550 (and K171565)	**Proposed Device:** OEC Elite with Enhanced Noise Reduction claims
X-ray Initiation and Termination	➢ Wired footswitch ➢ Wired hand switch	➢ Wired footswitch ➢ Wired hand switch ➢ **Optional wireless footswitch**
Cardiac Imaging	➢ Available with the 21 cm image receptor.	➢ Available with the 21 and **31 cm** image receptor.
Image Noise Reduction	➢ Image processing chain including noise modeling, filtering, reduction.	➢ Image processing chain including noise modeling, filtering, reduction. ➢ **Enhanced Noise Reduction**

Control Panel on C-arm	➢ Button actuated control panel and reference monitor.	➢ **Integrated touch screen control panel.**
Motorized C-arm motion feature	➢ No motion control feature.	➢ **Motorized motion control**
Enhanced Noise Reduction Claims	➢ No Enhanced Noise Reduction feature.	➢ **Claims for equivalence to a higher power system without an increase in radiation dose for both cardiac and vascular applications.**

The changes described above do not change the fundamental control mechanism, operating principle, energy type, and do not change the Intended Use of the predicate device.

Determination of Substantial Equivalence:

The device has successfully completed all testing per GE's quality system as well as addition engineering bench testing in support of this submission. The system has been tested and is compliant with the IEC 60601-1 Ed. 3 series, including IEC 60601-1-2, 60601-1-3, 60601-2-43, and 60601-2-54. 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
- 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.

Non-Clinical Testing

The verification and validation testing have been successfully completed as required by design control procedures under GE Healthcare's quality system. This includes risk management, software verification and validation testing, as well as image quality and dose performance using standard IQ metrics and QA phantoms.

Additional engineering bench testing was performed to substantiate the quantitative performance claims related to Enhanced Noise Reduction. Additionally, testing was performed to demonstrate the overall imaging performance of OEC Elite with Enhanced Noise Reduction using a wide variety of anthropomorphic phantoms.

Clinical Testing

OEC Elite with Enhanced Noise Reduction claims uses the identical imaging change, does not change the Indications for Use, and has equivalent/identical technological characteristics. This type of change 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.

Substantial Equivalence Conclusion:

The changes associated with OEC Elite with Enhanced Noise Reduction Claims do not change the Indications for Use or Intended Use. The OEC Elite with Enhanced Noise Reduction Claims' control mechanism, operating principle, and energy type have not changed from the predicate and reference devices. In addition, the OEC Elite with Enhanced Noise Reduction Claims complies with the same international and national standards, 21 CFR performance requirements and NEMA XR standards.

It has successfully completed design controls activities, including risk management, verification and validation. The verification and validation testing as well as the additional engineering bench testing that substantiated the claims did not raise any new questions of safety or efficacy, identify any new hazards, and did not have any unexpected results.

The scientific engineering bench testing methods used to evaluate the safety and effectiveness of OEC Elite's with Enhanced Noise Reduction characteristics and proposed claims are acceptable and demonstrate substantial equivalence.

We believe the OEC Elite with Enhanced Noise Reduction Claims is of comparable type and substantially equivalent to the predicate and reference devices, OEC Elite (K172550, K171565) and therefore is safe and effective for its intended use.