GE Hualun Medical Systems Co., Ltd. November 9, 2017
Lifeng Wang
Regulatory Affairs Manager
No 1 Yong Chang North Road
Beijing Economic Technological Development Zone
Beijing, 100176, China

Re: K172700
Trade/Device Name: OEC One™
Regulation Number: 21 CFR 892.1650
Regulation Name: Image-Intensified Fluoroscopic X-Ray System
Regulatory Class: Class II
Product Code: OWB, OXO, JAA
Dated: September 7, 2017
Received: September 7, 2017

Dear Lifeng Wang:

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.

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.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Robert Ochs

Robert 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)*

K172700

Device Name
OEC One™

Indications for Use *(Describe)*

The OEC One mobile C-arm system is designed to provide fluoroscopic and digital spot/film 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, 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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

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

Date:	Sep 7, 2017
Submitter:	GE HUALUN MEDICAL SYSTEMS CO. Ltd. No.1 Yong Chang North Road, Beijing Economic Technological Development Zone Beijing 100176, China
Manufacturer/ Manufacturing Location	GE HUALUN MEDICAL SYSTEMS CO. Ltd. No.1 Yong Chang North Road, Beijing Economic Technological Development Zone Beijing 100176, China
Primary Contact Person:	Lifeng Wang Regulatory Affairs Manager GE Healthcare +86 10 57083145 Lifeng.Wang@ge.com
Secondary Contact Person:	Helen Peng Regulatory Affairs Director GE Healthcare +1 262 424-8222 Hong.Peng@ge.com
Device Trade Name:	OEC One™
Classification Names:	Image-intensified fluoroscopic x-ray system
Device Class	Class II
Classification regulation:	21CFR 892.1650
Primary Product Code:	OXO
Secondary Product Code:	JAA, OWB
Predicate Device(s):	K123603 OEC Brivo, 892.1650, OXO
Device Description:	The OEC One™ is a mobile C-arm x-ray system to provide fluoroscopic images of the patient during diagnostic, interventional, and surgical procedures such as orthopedic, gastrointestinal, endoscopic, urologic, neurologic, critical care, and emergency procedures. These images help the physician visualize the patient's anatomy and localize clinical regions of interest. The system consists of a mobile stand with an articulating arm attached to it to support an image display monitor (widescreen monitor) and a TechView tablet, and a "C" shaped

	apparatus that has an image intensifier on the top of the C-arm and the X-ray Source assembly at the opposite end. The OEC One™ is capable of performing linear motions (vertical, horizontal) and rotational motions (orbital, lateral, wig-wag) that allows 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 subject device is labelled as OEC One.
Intended Use:	The OEC One™ mobile C-arm system is intended to provide fluoroscopic and digital spot/film images of the patient anatomy, interventional tools/devices, and/or contrast agents during diagnostic, interventional, and surgical procedures.
Indications for Use	The OEC One™ mobile C-arm system is designed to provide fluoroscopic and digital spot/film 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, critical care, and emergency procedures.
Technology:	The modified OEC One™ employs the same fundamental scientific technology as that of the unmodified predicate device(K123603). The primary change for the subject device was to integrate the separate mainframe and workstation of the predicate device into a compact configuration to save the space of the operation room with smaller foot print and to offer better workflow, ergonomics and usability. Additionally, a separate articulating arm attached to the mobile stand was added to support the single widescreen image display monitor and a TechView tablet and to offer more degrees of freedom for easier positioning and maneuverability. The software was updated primarily to support changing to a single image display monitor, adding a new TechView tablet, consolidation of user interface, and modifying existing features for Adaptive Dynamic Range Optimization(ARDO) and motion artifact reduction. Additionally, the software was also modified to add an Alternating Current (AC) recovery feature and to comply to NEMA XR-27(User Quality Mode) requirement.

Determination of Substantial Equivalence:

Summary of Non-Clinical Testing:

Verification and validation including hazard mitigation has been executed with results demonstrating the OEC One™ system met design input and user needs.

The system has been tested by an NRTL and certified 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 One™ system was developed under the GE Healthcare's 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
- Unit Testing (Sub System verification)
- Integration testing (System verification)
- Performance testing (Verification)
- Safety testing (Verification)
- Simulated use testing (Validation)

Additional engineering bench testing on image performance using anthropomorphic phantoms was also performed. 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 substantial equivalence was also based on software documentation for a "**Moderate**" level of concern device.

Clinical Testing:

Because OEC One's modification based on the predicate device does not change the system's intended use and represent equivalent technological characteristics, clinical studies are not required to support substantial equivalence.

Conclusion:

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 Healthcare's Quality Management System, we believe that the OEC One is of comparable type and substantially equivalent to the predicate device OEC Brivo Series (K123603).