DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

July 12, 2017

GE HUALUN MEDICAL SYSTEMS CO. LTD.
% Ms. Lifeng Wang
Regulatory Affairs Leader
No1 Yong Chang North Road
Beijing Economic Technological Development Zone
Beijing 100176 Beijing
CHINA

Re: K171800
Trade/Device Name: OEC Elite™ MiniView™
Regulation Number: 21 CFR 892.1650
Regulation Name: Image-intensified fluoroscopic x-ray system
Regulatory Class: II
Product Code: OXO, JAA
Dated: June 15, 2017
Received: June 16, 2017

Dear Ms. 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.

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 yours,

For

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)*

K171800

Device Name
OEC Elite™ MiniView™

Indications for Use *(Describe)*

The OEC Elite MiniView (mobile mini C-Arm) is designed to provide physicians with real time general fluoroscopic visualization of patients of all ages. It is intended to aid physicians and surgeons during diagnostic or therapeutic treatment/surgical procedures of the limbs/extremities and shoulders including, but not limited to, orthopedics and emergency medicine.

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:	June 16, 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 Elite™ MiniView™
Common/Usual Name:	Fluoroscopic X-Ray System, Mobile Mini Mobile C-Arm, Mini C-Arm
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
Predicate Device(s):	K160131, OEC Elite MiniView

Device Description:

The OEC Elite™ MiniView™ is a mobile fluoroscopic mini C-arm system that provides fluoroscopic images of patients of all ages during diagnostic, treatment, and surgical procedures of the shoulders, limbs, and extremities. The system consists of a C-arm attached to an image processing workstation. A CsI(Tl) -CMOS flat panel detector and the identical X-ray source monoblock are used for image acquisition.

The C-arm supports the high-voltage generator, X-ray tube, X-ray controls, collimator, and the FPD. The C-arm is capable of performing linear (vertical, horizontal, orbital) and rotational motions that allow the user to position the X-Ray imaging components at various angles and distances with respect to the patient extremity anatomy to be imaged. The C and support arm are mechanically balanced allowing for ease of movement and capable of being "locked" in place using an electronically controlled braking system. The workstation is a stable mobile platform that supports the C-arm, image display monitor(s), image processing equipment/software, recording devices, data input/output devices and power control systems.

The primary technology change for the subject device compared to the unmodified predicate OEC Elite MiniView, was to add an optional wireless footswitch which provides identical functionalities as the wired footswitch to control X-ray on and off.

Intended Use:

The OEC Elite™ MiniView™ (mobile mini C-arm) is intended to provide fluoroscopic images of the patient during diagnostic or therapeutic treatment/surgical procedures of the limbs/extremities and shoulders.

Indications for Use

The OEC Elite™ MiniView™ (mobile mini C-Arm) is designed to provide physicians with real time general fluoroscopic visualization of patients of all ages. It is intended to aid physicians and surgeons during diagnostic or therapeutic treatment/surgical procedures of the limbs/extremities and shoulders including, but not limited to, orthopedics and emergency medicine.

Technology:

The modified OEC Elite™ MiniView™ employs the same fundamental scientific technology as the unmodified predicate device. The proposed device will provide an optional off-the-shelf wireless foot switch uses 2.4GHz radio frequency technology with proprietary private protocols. The introduction of this wireless footswitch does not change any existing hardware or software of the predicated device. The new option is equivalent to the wired footswitch on the predicate in that the functionalities are identical. The wireless option provides placement flexibility and reduces cable clutter.

Determination of Substantial Equivalence:

Summary of Non-Clinical Testing:

The modified OEC Elite™ MiniView™ system with the wireless footswitch was developed under the GE Healthcare's design controls processes and overall quality management system.

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.

Risk management activities including using risk analysis to identify any potential issues incorporating the wireless footswitch were performed. These issues were reviewed and mitigated with inherent safe designs and labeling. The mitigations were verified and validated as a part of the design verification and validation testing that has been executed with acceptable results. This testing also includes the EMC and coexistence testing per the "Radio Frequency Wireless Technology in Medical Devices" Guidance for Industry and Food and Drug Administration Staff issued on August 14, 2013 (Wireless Guidance).

Clinical Testing:

The subject of this premarket submission, OEC Elite MiniView with the addition of the wireless footswitch, did not require clinical studies to support substantial equivalence.

Design verification and validation testing was performed to confirm that the safety and effectiveness of the devices has not been affected. The test plans and results have been executed with acceptable results.

Conclusion:

The OEC Elite MiniView incorporates a wireless footswitch for the user to initiate and terminate x-ray exposures as an option. The addition of the optional wireless footswitch to the system does not raise new questions on safety and effectiveness. The modified subject device has the same technological characteristics and perform as well as the unmodified predicate device and other similar devices that incorporate a wireless footswitch currently on the market.

Based on the successful verification and validation testing, additional engineering bench testing per the FDA Wireless guidance, conformance to standards, and development under GE's Quality Management System, we believe that the modified OEC MiniView is of comparable type and substantially equivalent to the predicate device OEC Elite MiniView (K160131), and therefore is safe and effective for its intended use.