DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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June 21, 2016

GE Hangwei Medical Systems Co., Ltd
Lifeng Wang
Regulatory Affairs Leader
No. 1 Yongchang North Road
Beijing Economic & Technological Development
Beijing P.R. 100176
CHINA

Re: K160131
Trade/Device Name: OEC Elite MiniView
Regulation Number: 21 CFR 892.1650
Regulation Name: Image-intensified fluoroscopic x-ray system
Regulatory Class: Class II
Product Code: OXO, JAA
Dated: 5/05/2016
Received: 5/09/2016

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.

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" (21CFR 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,

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)*

K160131

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.

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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: January 18, 2016

Submitter:
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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
Marketed Device	OEC Elite™ MiniView™ is a mobile fluoroscopic mini C-Arm system built upon the existing technologies of the predicate device OEC Mini 6800 (K992506) and reference devices. It is of comparable type and substantially equivalent to its predicate device OEC Mini 6800 and the identified reference devices Hologic Insight- FD Mini C-arm and OEC Brivo Series. The intended use has not changed. The proposed device's indications for use have been revised to better align with actual patient populations and the system capabilities as substantiated in the testing and evaluations provided. The system is labeled as the OEC Elite™ MiniView™
Predicate Device(s):	K992506, Mini 6800 Digital Mobile C-arm
Reference Device(s)	K120388, Hologic Insight- FD mini C-arm Fluoroscopic Imaging System K123603 GE's OEC Brivo Series
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.

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 OEC Elite™ MiniView™ employs the same fundamental scientific technology as that of the predicate device OEC Mini 6800(K992506) and the reference device Hologic Insight FD Mini C-arm (K120388).

Its software uses virtually the same architectural design of the reference device OEC Brivo Series (K123603) with modifications being made to support the flat panel detector, the necessary imaging and post processing applications related to the FPD, and device specific features/functionality.

The primary change on the C-arm is the replacement of the predicate's conventional image intensifier with Thallium-doped Cesium Iodide [CsI(Tl)] solid state flat panel X-ray detector with Complementary Metal Oxide Semiconductor (CMOS) photodiodes. The X-Ray source monoblock remains unchanged from that of the OEC Mini 6800. On the workstation, the main hardware changes include using an up to date computer that offers more image storage, processing power and speed, and LCD monitors.

The mechanical design is improved for usability, maneuverability, and positioning. The weight of the C-arm is reduced and it is better balanced. The system is equipped with and one-button activated powered braking system that secures key joints to eliminate drift.

The tables below compare the main performance data of the proposed device with the predicate device and the referenced devices.

Table 1 Significant Differences between OEC Elite™ MiniView™ and OEC Mini 6800 Digital Mobile C-arm(K992506)

	Predicate Device OEC Mini 6800 Digital Mobile C-arm K992506	Proposed Device OEC Elite™ MiniView™	Discussion of Differences
Monitor	➢ Dual 16" CRT Monitors with 1000 line resolution	➢ Dual 19" Monochrome LCD Monitors with 1280 x 1024 resolution	Substantially Equivalent The monitor displays on the proposed device has been updated to a LCD monitors. This change was driven by IT technology advancement by using a more state of the art display technology which is considered adequate for viewing extremities and represents an improvement over the CRT monitors of the predicate device and this change did not raise any new safety and effectiveness concerns.
Display articulation	➢ Fixed	➢ Small extension with 450° swivel	Substantially Equivalent The proposed device has added display articulation, to improve workflow for the end user allowing the monitor to be extended and rotated +180/-270 degrees. This change did not raise any new safety and effectiveness concerns.
Power Failure Protection	➢ N/A	➢ Backup Battery	Substantially Equivalent The proposed device has added a backup battery to protect the data integrity in hard disk drive when the device receives a sudden loss of power. It also allows for limited additional exposure time for the ability to

			controllably exit or finish an in-progress procedure. This change did not raise any new safety and effectiveness concerns.
Physical Dimensions	➢ Depth: 17.7" (45 cm) ➢ Free Space: 13.8" (35 cm) ➢ Orbital Rotation: 115° ➢ Lateral Rotation: +/- 220° ➢ Vertical Travel: 27" (70 cm) ➢ Panning Motion: 365°	➢ Depth: 18" (46 cm) ➢ Free Space: 13.4" (34 cm) ➢ Pivoting Orbital Rotation: 120° ➢ Lateral Rotation: 380° ➢ Horizontal Travel: 77.2" (196 cm) ➢ Vertical Travel: 33.4" (85cm) ➢ Panning Motion: 366°	Substantially Equivalent The proposed device improved the physical dimensions for workflow purposes by incorporating a pivoting orbital rotation motion. All design changes meet IEC safety criteria. This change did not raise any new safety and effectiveness concerns.
Image Storage	➢ 800 Images	➢ 100,000 Images	Substantially Equivalent The proposed device has enhanced the system's storage ability to store more images. This change did not raise any new safety and effectiveness concerns.
Removable Data Storage	➢ Floppy disk	➢ USB port	Substantially Equivalent The proposed device has updated the technology to incorporate a USB port to accommodate standard data retrieval storage and export needs. This change was driven by IT technology advancement by using a more state of the art media which is the USB instead of the out of date floppy disk which is not used by the industry any more.

			This change did not raise any new safety and effectiveness concerns.
Dose Area Product (DAP)	➢ N/A	➢ Dose Area Product (DAP)	Substantially Equivalent The proposed device has added the ability for the physician to see the DAP displayed for each exam. This change did not raise any new safety and effectiveness concerns.
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 ➢ Edge enhancement ➢ Zoom & Roam ➢ Image rotation ➢ Image flip/ invert ➢ Smart Metal	➢ 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 ➢ Edge enhancement ➢ Zoom & Roam ➢ Image rotation ➢ Image flip/ invert ➢ Smart Metal ➢ AutoTrak	Substantially Equivalent The proposed device provides AutoTrak feature to automatically seek anatomy in the imaging field and select optimal technique to reduce the need for taking additional X-ray images. This is a workflow improvement and did not raise new safety and effectiveness concerns.

Table 2 Significant Differences between OEC Elite™ MiniView™ and OEC Brivo Mobile C-arm (K123603) device

	Reference Device OEC Brivo Mobile C-arm - K123603	Proposed Device OEC Elite™ MiniView™	Discussion of Differences
Software	64-bit Linux, with a Windows-like operating system Arbitrated Internal Communication Windows like user interface	64-bit Linux, with a Windows-like operating system Arbitrated Internal Communication Windows like user interface	Substantially Equivalent The operating system is a contemporary software OS common in current medical devices. The proposed device's software platform is based on the reference device OEC Brivo (K123603) software platform with modifications specifically made to support the proposed device's COMS detector and associated changes. Leveraging the OEC Brivo software platform and making necessary modifications did not raise any new safety or efficacy concern and is determined to be substantially equivalent.
Connectivity	Ethernet Wired Wireless (Optional)	Ethernet Wired Wireless (Optional)	Substantially Equivalent Both devices offer a wireless adaptor meant for DICOM communication with the archiving systems such as PACS and RIS, and DICOM printers on the hospital's private network. It is intended

			to be an alternate means to the wired communication configuration installed on all systems by default. The change in the proposed device as compared to the reference device OEC Brivo system is that it used a more up to date wireless technology, both of which confirm to the FCC standards and same wireless protocols EMC testing per IEC with the WiFi adaptor integrated in the system as well as additional coexistence testing conducted per the FDA guidance titled "Radio Frequency Wireless Technology in Medical Devices" issued August 14th, 2013 demonstrated that having the WiFi option in the proposed device does not affect the safety or efficacy of the device.

Table 3 Significant Differences between OEC Elite™ MiniView™ and Hologic® Insight-FD Mini C-Arm Fluoroscopic Imaging System (K120388) devices

	Reference Device Hologic® Insight-FD Mini C-Arm Fluoroscopic Imaging System K120388	Proposed Device OEC Elite™ MiniView™	Discussion of Differences
Image Receptor	CMOS Flat Panel Detector	CMOS Flat Panel Detector	Substantially Equivalent The proposed device uses

			same CMOS flat panel technology. The change to a flat panel detector does not affect the safety or efficacy of the device.
	Pixel Size: 75 Microns	Pixel Size:100 Microns	Substantially Equivalent: The proposed device's pixel size is larger for reducing image noise. The resolution is higher than the Image Intensifier on the predicate. The difference does not affect the safety or efficacy of the device.
	Array Size: 2k x 1.5k	Array Size: 1.3k x 1.3k	Substantially Equivalent The array size gives a 5 inch square detector which is adequate for viewing extremities. The difference does not affect the safety or efficacy of the device.
	Full Field: 14.5 cm x 11.5 cm (5.7" x 4.5") Limited Field: 11 cm (4.3") square	Full Field: 13 cm (5.1") circle Limited Field: 10 cm (4") circle	Substantially Equivalent Full field and limited field sizes in proposed device are slightly smaller than the reference device Hologic® Insight-FD K120388. These sizes are appropriate for viewing extremities.

The changes and differences described above do not change the control mechanism, operating principle, energy type, and intended use found on predicate and reference devices.

Adverse Effects on Health

Potential electrical, mechanical, and radiation hazards are identified in risk management including hazard analysis and controlled by:

- System verification and validation to ensure performance to specifications, Federal Regulations, and user requirements.
- Adherence and certification to industry and international standards. AAMI/ES and IEC60601-1 Ed.3 and associated collateral and particular standards including IEC 60601-2-54 and IEC 60601-2-43.
- Meeting the applicable CDRH 21CFR subchapter J performance requirements.

The device is designed and manufactured under the Quality System Regulations

of 21CFR 820.

Determination of Substantial Equivalence:

Summary of Engineering Bench Testing:

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

The system has been NRTL tested 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 Elite™ MiniView™ system was developed under the GE Healthcare's design controls processes, software development life cycle, and overall quality management system. The following quality assurance measures were applied to the development of the system:

- Risk Analysis
- Required Reviews
- Design Reviews
- Testing on unit level (Module verification)
- Integration testing (System verification)
- Performance testing (Verification)
- Safety testing (Verification)
- Simulated use testing (Validation)

Additional engineering bench testing was performed including: the non-clinical testing identified in the guidance for submission of 510(k)s for Solid State X-Ray Imaging Devices (SSXI); demonstration of system performance; and an imaging performance evaluation using anthropomorphic phantoms (including a pediatric anthropomorphic phantom). All of 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.

A cadaver imaging evaluation that compared the imaging performance of the subject device to the predicate was also performed by two independent physicians. A total of nineteen orthopedic procedures across a variety of extremity anatomies were performed using two cadavers. Given that the subject device is indicated for extremity-only use, which is characterized by orthopedic / musculoskeletal-related diagnostic and therapeutic/surgical procedures, it was determined that a human cadaver study was appropriate. For all procedures, the study confirmed the clinical capability and overall quality of the images produced by the OEC Elite™ MiniView™ was at least equivalent to that of the Mini 6800 Digital Mobile C-Arm.

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

Clinical Testing:

Cadaver images were provided; these images were not necessary to establish substantial equivalence based on the modifications to the device and the bench data provided (bench data was used to compare the modified detector to the reference detector) but they provide further evidence in addition to the laboratory performance data to show that the complete system works as intended. The OEC Elite™ MiniView™ mobile fluoroscopic mini C-arm system did not require live human clinical studies to support substantial equivalence.

Conclusion:

Based on the successful verification and validation testing, additional bench testing, the cadaver study, conformance to standards, and development under GE Healthcare's quality system, GE Healthcare believes that the OEC Elite™ MiniView™ is of comparable type and substantially equivalent to the predicate device OEC Mini 6800(K992506) with support from the reference devices, and therefore is safe and effective for its intended use.