K132027

MAY 0 1 2014

510(k) Summary

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

Date: November 20, 2013

Submitter: GE Healthcare Surgery
384 Wright Brothers Drive
Salt Lake City, UT 84116

Primary Contact Person: Karen Russell
Regulatory Affairs Leader
GE Healthcare Surgery
Phone: (801) 536-4930 Fax: (801) 517-6566

Secondary Contact Person: Jeff Wagner
Regulatory Affairs Manager
GE Healthcare Surgery
Phone: (801) 517-6415 Fax: (801) 517-6566

Device: (Trade Name): OEC® 9800 Plus

Common/Usual Name: Mobile Fluoroscopic Imaging System

Classification Names: 21 CFR 892.1650 Image-intensified fluoroscopic x-ray system

Product Code: 90OWB, 90OXO and 90JAA

Predicate Device(s): K111551 OEC® 9800 Plus

Device Description: The OEC® 9800 Plus is a system used to assist trained Surgeons. The system is used to provide X-Ray images while the Surgeon performs a medical procedure. Images from the system help the Surgeon to visualize the patients' anatomy. This visualization helps to localize surgical regions of interest and pathology. The images provide real-time visualization and records of pre-surgical anatomy, in vivo-surgical activity and post surgical outcomes.

The proposed device will add an alternative supplier for the X-Ray Tube. The current tube and the proposed tube have the same specifications and will be interchangeable. Verification activities confirmed that the proposed tube meets the same specification as the current supplier's tube.

The proposed device will add an alternative supplier for the Radiological Imaging Unit (RIU) or Image Intensifier. The current RIU and the proposed RIU have the same specifications and will be interchangeable. Verification activities confirmed that the alternate RIU meets the same specification as the current supplier's RIU.

The proposed device will provide an optional wireless foot switch and hand switch. The new option is equivalent to the predicate in that functionality is identical. The wireless option provides placement flexibility and reduced cable clutter.

Two printed circuit board assemblies have been combined into a single board in the proposed device due to parts obsolescence. Both the proposed and predicate assemblies share common specifications as confirmed through verification testing.

The proposed device will include a LCD monitor which replaces the obsolete CRT monitor. Both the proposed and predicate assemblies share common specifications as confirmed through verification testing.

The proposed device includes an alternative solid state drive. This drive provides a faster write speed. Both drives meet their specifications.

The proposed device will include a different model of an OEM injector system. Both the proposed and predicate OEM injector systems share common specifications as confirmed through verification testing.

Intended Use:

The Series OEC® 9800 Plus is designed to provide fluoroscopic and spot-film imaging of the patient during diagnostic, surgical and interventional procedures. Clinical application may include cholangiography, endoscopy, urologic, orthopedic, neurologic, vascular, cardiac, critical care and emergency room procedures.

Technology: The modified OEC® 9800 Plus device employs the same fundamental scientific technology as the predicate device.

Determination of Substantial Equivalence:

Summary of Non-Clinical Tests

The following quality assurance measures were applied to the development of the proposed device: Risk Analysis, Requirements Reviews, Design Reviews and testing which included component, subsystem, and system.

Design verification methodology was hierarchal. When component development was completed, component level tests were executed. Upon completion of component testing, subsystem and system verification were also performed. The Design Verification of the OEC 9800 Plus confirms that design output meets design input requirements.

Functional testing was performed which included mechanical, electrical, and overall system tests. X-ray acquisition, X-ray control and indication, patient data management, imaging modes (basic and advanced), image quality acquisition and assessment, image processing and presentation, screen measurements, motorized system, and subsystem mechanical tests were performed. Performance testing included image quality, and subsystem performance.

Product Simulated Use Testing was used to evaluate whether the device meets user needs and intended uses by simulating a use environment, and having testing performed by users with relevant clinical experience. The functional requirements of image storage and recall capability were validated using the proposed device. The proposed device was also used to produce images that were evaluated to confirm the new monitor met user needs and intended use.

Safety testing was performed in laboratory settings by qualified technicians to confirm that the product met the requirements of the standards listed in Table 1 below.

The OEC® 9800 Plus complies with the voluntary and mandatory standards listed in Table 1 below.

Summary of Clinical Tests

The OEC 9800 Plus is based on modifications to a cleared predicate device. There were no changes to the intended use. Clinical studies on living human patients were not necessary to support substantial equivalence.

Conclusion: The verification and validation testing described above demonstrates that the OEC® 9800 Plus is safe, effective, and performs, for its intended use, in an equivalent manner to the predicate device and in accordance with its labeling. OEC® 9800 Plus is substantially equivalent in performance to the predicate OEC® 9800 Plus (K111551).

Table 1 Product Standards Compliance

Standards No.	Standards Organization	Standards Title	Version	Date
21 CFR 1020.30-32	FDA	Federal Performance Standard for Diagnostic X-ray Systems	2012	2012
60601-1	UL	Medical Electrical Equipment, Part 1: General Requirements for Safety	1st edition	2003
60601-1	IEC	Medical Electrical Equipment, Part 1: General Requirements for Safety	A1 (1991) and A2 (1995)	1988, 1991, 1995
60601-1-2	IEC	Collateral Std: Electromagnetic Compatibility	2.1 edition	2004
60601-1-3	IEC	Collateral Std: Radiation Protection in Diagnostic X-ray Equipment	1st edition	1994
60601-1-4	IEC	Collateral Std: Radiation Protection in Diagnostic X-ray Equipment	1.1 edition (+A1)	2000
60601-1-6	IEC	Collateral Std: General Requirements for Basic Safety and Essential Performance	2nd edition	2006
60601-2-7	IEC	Particular Std: Safety of H.V. Diagnostic X-ray Generators	2nd edition	1998
60601-2-28	IEC	Particular Std: Safety of X-ray Tube and X-ray Source Assemblies	1st edition	1993
60601-2-32	IEC	Particular Std: Safety of Associated Equipment of X-ray Equipment	1st edition	1994
NEPA 99	NFPA	US National Electric Code Health Care Facilities	2005	2005
DICOM	DICOM	US National Electric Code Health Care Facilities	2008	2008

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center -
WO66-G609
Silver Spring, MD 20993-0002

May 1, 2014

GE Healthcare Surgery
Jeff Wagner
Regulatory Affairs Manager
384 Wright Brothers Drive
Salt Lake City, Utah 84116

Re: K132027/S004
Trade/Device Name: OEC 9800 Plus
Regulation Number: 21 CFR 892.1650
Regulation Name: Image-Intensified Fluoroscopic X-Ray System
Regulatory Class: Class II
Product Code: OWB, OXO, JAA
Dated: February 27, 2014
Received: April 2, 2014

Dear Mr. Wagner:

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.

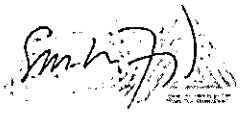
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further 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 Small Manufacturers, International and Consumer Assistance 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 Small Manufacturers, International and Consumer Assistance 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

Janine M. Morris
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: December 31, 2013
See PRA Statement on last page.

510(k) Number *(if known)*
K132027

Device Name
GE OEC® 9800 Plus

Indications for Use *(Describe)*
Indications for Use: The OEC 9800 Plus is designed to provide fluoroscopic and spot-film imaging of the patient during diagnostic, surgical and interventional procedures. Clinical application may include cholangiography, endoscopic, urologic, orthopedic, neurologic, vascular, cardiac, critical care and emergency room procedures.

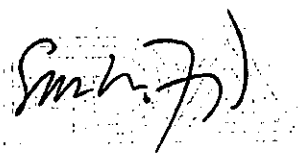
Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*



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