APR - 6 2012

K120613

GE Healthcare

510(k) Premarket Notification Submission

510(k) Summary

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

Date: February 24, 2012

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

Primary Contact Person: Gerald Buss
Director Regulatory Affairs
GE Healthcare Surgery
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Regulatory Affairs Leader
GE Healthcare Surgery
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Device: (Trade Name): OEC® 9900 Elite

Common/Usual Name: Mobile Fluoroscopic Imaging System

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

Product Code: 90OXO and 90JAA

Predicate Device(s): K082781 OEC® 9900 Elite

Device Description: The OEC® 9900 Elite is a system used to assist trained physicians. The system is used to provide X-Ray images while the physician performs a medical procedure. Images from the system help the physician 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 system is composed of two primary physical elements. The first is referred to as the "C-Arm" because of its "C" shaped image gantry; the second referred to as the "Workstation" because this is the primary user interface to the system.

The system is used in different surgical procedures. Orthopedic physicians may use the system to help perform hip replacements and reconstructions of badly fractured bones. Orthopedic physicians may use the system to help perform hip replacements and reconstructions of badly fractured bones. Vascular physicians may use the system to perform blood flow studies.

Cardiologists may use the system to help see if there are blockages in some of the key arteries supplying blood to the heart. The procedures that these physicians perform are broadly referred to as "Clinical Applications". The system is controlled and run in a clinical environment.

The system employs X-Rays as its imaging technology. An X-Ray Generator located in the base of the C-Arm creates high voltage. High voltage is carried to the X-Ray tube across a set of cables. The X-Ray tube emits X-Rays that are directed toward the patient under the control of the operator. The Physician defines the desired view for the specific clinical procedure and directs the operator. The X-Rays pass through the patient and are captured by the image intensifier (II). Image intensifier images are captured by a camera and displayed on the image monitor located on the Workstation. The Physician or system operator view the images as they are displayed and they may choose to store the images for later review.

In order to perform these procedures different views of the human anatomy are required, so the system is designed with the ability to rotate and translate the C-Arm's image gantry to obtain different viewing angles. In addition since there is variation in thickness and density of the anatomy the system operator has the ability to adjust the X-Ray Generator technique, image size and orientation to account for the anatomical differences.

Intended Use:

The OEC® 9900 Elite Mobile Fluoroscopy System is designed to provide fluoroscopic and spot-film images of the patient during diagnostic, surgical and interventional procedures. Examples of clinical application may include cholangiography, endoscopy, urologic, orthopedic, neurologic, vascular, cardiac, critical care and emergency room procedures.

Technology:

The modified OEC® 9900 Elite device employs the same fundamental scientific technology as the predicate device.

Determination of Substantial Equivalence:	The OEC® 9900 Elite and its application comply with voluntary standards as detailed in Section 9, of this premarket submission. The modifications from the predicate device OEC® 9900 Elite were completed in accordance with GE Healthcare Surgery's quality management system design controls. Engineering testing and standards compliance testing were successfully conducted and did not raise any new safety questions or concerns or identify new risks. Information is included with this 510(k) submission that supports this determination.
Conclusion:	GE Healthcare considers the modified GE OEC® 9900 Elite to be safe, as effective, and performance is substantially equivalent to the predicate device OEC® 9900 Elite (K082781).

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

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

Mr. Gerald Buss
Director Regulatory Affairs
GE Healthcare Surgery
384 Wright Brothers Drive
SALT LAKE CITY UT 84116

APR - 6 2012

Re: K120613
Trade/Device Name: GE OEC 9900 Elite
Regulation Number: 21 CFR 892.1650
Regulation Name: Image-intensified fluoroscopic x-ray system
Regulatory Class: II
Product Code: OWB, OXO and JAA
Dated: March 15, 2012
Received: March 16, 2012

Dear Mr. Buss:

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.

If your device is classified (see above) into class II (Special Controls), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. 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 Parts 801 and 809); medical device reporting (reporting of

medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Parts 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. 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/cdrh/industry/support/index.html.

Sincerely Yours,

Janine M. Morris
Acting Director
Division of Radiological Devices
Office of In Vitro Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

K120613

GE Healthcare

510(k) Premarket Notification Submission

INDICATIONS FOR USE

510(k) Number (if known):

Device Name: GE OEC 9900 Elite

Indications for Use:

The OEC® 9900 Elite is designed to provide fluoroscopic and spot-film images of the patient during diagnostic, surgical and interventional procedures. Examples of clinical application may include cholangiography, endoscopy, urologic, orthopedic, neurologic, vascular, cardiac, critical care and emergency room procedures.

Prescription Use ✓ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (Part 21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Radiological Devices
Office of In Vitro Diagnostic Device Evaluation and Safety

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