K122234

AUG 16 2012

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: August 3, 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
Phone: (801) 517-6591 Fax: (801) 517-6566

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

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, 90JAA, and OWB

Predicate Device(s): K120613 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 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 service platform to allow the user to connect to hospital intranet PACS system. The predicate product features a hard-wired connection. Verification testing confirmed that all specifications, including data security, were met.

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

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.

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. The comparison chart reveals that functions performed by the predicate device are performed by the proposed device.

Determination of Substantial Equivalence: Verification testing has confirmed that 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 as safe, as effective, and perform substantially equivalent to the predicate device OEC® 9900 Elite (K120613).

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

AUG 16 2012

Mr. Gerald Buss
Director Regulatory Affairs
GE Healthcare Surgery (GE OEC Medical Systems, Inc.)
384 Wright Brothers Drive
SALT LAKE CITY UT 84116

Re: K122234
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: July 20, 2012
Received: July 26, 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

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 ✓ AND/OR Over-The-Counter Use_____
(Part 21 CFR 801 Subpart D) (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
OIVD
510k K122234