510(k) SUMMARY

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR §807.92.

AUG 15 2006

Date:	June 21, 2006
Name of Submitter:	GE OEC Medical Systems, Inc. 384 Wright Brothers Drive Salt Lake City, UT 84116 801-536-4525 (F) 801-328-4300
Corresponding Official:	Greg L. Hansen Safety & Regulatory Engineer
Device Proprietary Name:	GE OEC 9900 Plus
Classification Name:	Image Intensified Fluoroscopic X-ray System with Image Processing System / Mobile X-ray system.
Common/Usual Names:	Fluoroscopic Imaging System or Mobile C-arm.
Substantial Equivalence:	The GE OEC 9900 Plus Mobile Digital C-Arm is substantially equivalent to the: • GE OEC 9900 Elite Mobile C-Arm (K041932) marketed by GE OEC Medical Systems, Inc. • GE OEC 9900 Elite^{NAV} Mobile C-Arm (K041931) marketed by GE OEC Medical Systems, Inc.

Indications for Use

- The 9900 Plus Mobile Fluoroscopy System is designed to provide fluoroscopic images of human anatomy 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. The digital fluoroscopic imaging systems are intended to replace fluoroscopic system images obtained through image intensifier technology.

- The 9900 Plus 3D option is a software option, which reconstructs 3D volumes from Rotational Fluoroscopy acquisition to provide images that assist the physician in diagnosis, surgical planning, interventional procedures and treatment follow-up. 9900 Plus 3D is intended for imaging bone and soft tissues as well as other internal body structures. 9900 Plus 3D is not intended for mammography applications.

- The surgical Navigation feature is intended as an aid to the surgeon for locating anatomical structures anywhere on the human body during either open or percutaneous procedures. It is indicated for any medical condition that may benefit from the use of stereotactic surgery and which provides a reference to rigid anatomical structures such as sinus, skull, long bone or vertebra visible on fluoroscopic images. The system may be used for other imaging applications at the physicians discretion.

General Description

The GE OEC 9900 Plus is a digital image intensified fluoroscopic mobile C-arm system. It consists of a C-arm that supports a high-voltage generator, X-ray tube, X-ray controls, flat-panel digital detector, and LCD monitors. The C-arm is designed to perform linear and rotational motions that allow the user to position the X-ray imaging components at various angles and distances with respect to the patient. The GE OEC Workstation is a mobile platform that provides image display screens, image processing, recording, and printing devices.

Interfaces are provided for optional peripheral devices such as thermal or laser printer, video recording devices, and display monitors. Video outputs are compatible with RS-170 format for domestic markets, CCIR format for international markets, and DICOM. An auxillary connection is provided for an angiographic injector system to facilitate synchronization of angiographic images during contrast media injections.

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. Greg Hansen
Safety & Regulatory Engineer
GE OEC Medical Systems, Inc.
384 Write Brothers Drive
SALT LAKE CITY UT 74116

JUL 30 2012

Re: K061953
Trade/Device Name: GE OEC 9900 Plus
Regulation Number: 21 CFR 892.1650
Regulation Name: Image-intensified fluoroscopic x-ray system
Regulatory Class: II
Product Code: OWB, JAA and OXO
Dated: June 21, 2006
Received: July 10, 2006

Dear Mr. Hansen

This letter corrects our substantially equivalent letter of August 15, 2006.

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.

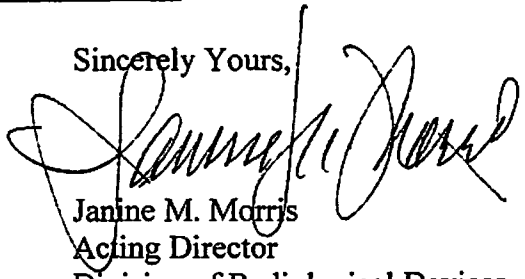
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's 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 Statement

Applicant: GE OEC Medical Systems, Inc.

510(k) No. (if known): K061953

Device name: GE OEC 9900 Plus

Indications for use:

- The 9900 Plus Mobile Fluoroscopy System is designed to provide fluoroscopic images of human anatomy 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. The digital fluoroscopic imaging systems are intended to replace fluoroscopic system images obtained through image intensifier technology.

- The 9900 Plus 3D option is a software option, which reconstructs 3D volumes from Rotational Fluoroscopy acquisition to provide images that assist the physician in diagnosis, surgical planning, interventional procedures and treatment follow-up. 9900 Plus 3D is intended for imaging bone and soft tissues as well as other internal body structures. 9900 Plus 3D is not intended for mammography applications.

- The surgical Navigation feature is intended as an aid to the surgeon for locating anatomical structures anywhere on the human body during either open or percutaneous procedures. It is indicated for any medical condition that may benefit from the use of stereotactic surgery and which provides a reference to rigid anatomical structures such as sinus, skull, long bone or vertebra visible on fluoroscopic images. The system may be used for other imaging applications at the physicians discretion.

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

Concurrence of CDRH Office of Device Evaluation (ODE)

Nancy C Brogdon

(Division Sign-Off)
Division of Reproductive, Abdominal and Radiological Devices
510(k) Number K061953

Prescription Use ✓ OR Over-The-Counter _____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)