K073543

MAY - 2 2008

Section 5 510(k) Summary

The following information is being submitted in accordance with the requirements of 21 CFR 807.92.

Company Name:	GE Healthcare Surgery
Address:	384 Wright Brothers Drive Salt Lake City, UT 84116
Contact Person:	Maria C. Frame Vice President Quality Assurance and Regulatory Affairs GE Healthcare Surgery Phone: (801) 517 6440 Fax: (801) 517 6566
Preparation Date:	December 14, 2007
Device (Trade Name):	OEC® 9900 Elite
Common/Usual Name:	Mobile Fluoroscopic Imaging System
Classification Names:	21 CFR 892.1650 and 892.1720 (either) Image-intensified fluoroscopic x-ray system and Mobile x-ray system. Product Code: 90JAA and 90IZL.
Predicate Device:	K041932 OEC Olympus Fluoroscopic Imaging System
Device Description:	The OEC® 9900 Elite Mobile Fluoroscopy System is an image intensified fluoroscopic system consisting of two mobile units: a Mainframe (C-Arm) and a Workstation. The Mainframe (C-Arm) is comprised of a high voltage generator, x-ray control, and a "C" shaped apparatus, which supports an X-ray tube and an image intensifier. The Mainframe 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 Workstation is a mobile platform that supports image display monitors, image processing and recording devices. Interfaces are provided for optional peripheral devices such as thermal or instant film printers.
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, critical care and emergency room procedures. The system may be used for other imaging applications at the physician's discretion.
Technology:	The OEC® 9900 Elite employs the same fundamental scientific technology as its predicate device. An uninterruptible power supply was added to provide additional safety to image and demographic data in the event of a power outage.
Determination of Substantial Equivalence:	The demonstration of substantial equivalence is based on a comparison of features to the predicate device and an assessment of non-clinical performance data. Information is included with this 510(k) submission that supports this determination.
Conclusion:	Performance testing included within this 510(k) demonstrates that the OEC® 9900 Elite is safe, effective and performs in an equivalent manner to the predicate device, with improved reliability and in accordance with its labeling.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY - 2 2008

Ms. Maria C. Frame
Vice President Quality Assurance and Regulatory Affairs
GE Healthcare Surgery (GE OEC Medical Systems, Inc.)
384 Write Brothers Drive
SALT LAKE CITY UT 84116

Re: K073543
Trade/Device Name: OEC® 9900 Elite
Regulation Number: 21 CFR 892.1650
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: JAA
Dated: December 14, 2007
Received: December 17, 2007

Dear Ms. Frame:

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 either class II (Special Controls) or class III (PMA), it may be subject to such 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); 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.

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 Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter.

21 CFR 876.xxxx	(Gastroenterology/Renal/Urology)	240-276-0115
21 CFR 884.xxxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 892.xxxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. 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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Nancy C Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Section 4 Indications For Use

510(k) Number (if known):

Device Name: OEC® 9900 Elite

Indications for 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, critical care and emergency room procedures. The system may be used for other imaging applications at the physician's discretion.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

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

(Optional Format 1-2-96)

(Division Sign-Off)
Division of Reproductive, Abdominal and Radiological Devices
510(k) Number K073543