SEP 17 2002

K022069

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.

Date:	June 21, 2002
Name of Submitter:	GE OEC Medical Systems 384 Wright Brothers Drive Salt Lake City, UT 84116 801-874-778
Corresponding Official:	Bill Gislason Vice President, Quality Assurance, Regulatory and Reliability
Device Proprietary Name:	OEC® FluoroTrak™ 9800 Plus
Classification Name:	Image Intensified Fluoroscopic X-ray System with Image Processing System
Common/Usual Names:	Fluoroscopic Imaging System with Interactive Image Guided Surgical System
Substantial Equivalence:	The OEC FluoroTrak 9800 Plus is substantially equivalent to the OEC 9800 Mobile Digital Imaging System (K974355) marketed by GE OEC Medical Systems, Inc. and the InstaTrak 3000 System with FluoroTrak Module (K994270) marketed by Visualization Technology, Inc.

Indications for Use

The OEC FluoroTrak 9800 Plus provides the physician with fluoroscopic imaging during diagnostic, surgical and interventional procedures. 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.

General Description

The OEC FluoroTrak 9800 Plus is the result of mechanically integrating the Instatrak 3000 System with FluoroTrak Module (marketed by Visualization Technology, Inc.) into the workstation of the OEC 9800 Mobile Imaging System.

The 9800 Mobile Imaging System is an image intensified fluoroscopic system consisting of a mobile C-arm and OEC Workstation. The C-arm supports the high-voltage generator, x-ray tube, x-ray controls, and image intensifier. 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 OEC workstation is a mobile platform that supports image display monitors, image processing and recording devices.

The InstaTrak 3000 System is an image guidance system indicated for use during sinus, skull base, cranial and axial skeletal procedures. Using the InstaTrak 3000, the surgeon can readily identify the immediate location and position of the surgical instrument during the indicated procedure.

The InstaTrak 3000 System allows the surgeon to view reconstructed two-dimensional images of the patient's anatomy in response to an electromagnetically tracked surgical instrument. This indicates the position of the tracked surgical instrument with regard to the patient's anatomy based on pre-operative medical images.

The InstaTrak 3000 System with FluoroTrak Module (K994270) is being mechanically integrated into the workstation of the OEC 9800 Mobile Imaging System (K974355) to form the system configuration marketed as the OEC FluoroTrak 9800 Plus. The intended use of both the InstaTrak 3000 System with FluoroTrak Module and the OEC 9800 Mobile Imaging System remains the same as described in their respective original 510(k)s.

Product Standards

The OEC FluoroTrak 9800 Plus is designed in accordance with product safety and performance requirements established in the following standards:

21 CFR 1020.30-32	Federal Performance Standard for Diagnostic X-ray Systems
ANSI/NFPA 70 & 99	National Electrical Code and Standard for Health Care Facilities
UL 2601	Medical Electrical Equipment
CSA-C22.2 No. 601.1-M90	Medical Electrical Equipment
IEC 60601-1	Medical Electrical Equipment, General Requirements for Safety
IEC 60601-1-2	Medical Electrical Equipment, Electromagnetic Compatibility
IEC 60601-1-3	Medical Electrical Equipment, Radiation Protection in Diagnostic X-ray
IEC 60601-1-4	Medical Electrical Equipment, Programmable Electrical Medical Systems
IEC 60601-2-7	Medical Electrical Equipment, HV/X-ray Generators
IEC 60601-2-28	Medical Electrical Equipment, X-ray Tube and Source Assemblies
IEC 60601-2-32	Medical Electrical Equipment, Safety of Associated X-ray Equipment
93/42/EEC - Annex 1	Essential Requirements of the Medical Devices Directive

This concludes this 510(k) Summary.

GE OEC MEDICAL SYSTEMS, INC.

Bill Gislason

Bill Gislason
Vice President, Quality Assurance, Regulatory, and Reliability

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

Mr. Bill Gislason
Vice President, Quality Assurance,
Regulatory and Reliability
GE OEC Medical Systems, Inc.
384 Wright Brothers Drive
SALT LAKE CITY UT 84116-2862

MAY 22 2012

Re: K022069
Trade/Device Name: OEC FluoroTrak 9800 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 24, 2002
Received: June 25, 2002

Dear Mr. Gislason:

This letter corrects our substantially equivalent letter of November 14, 2011.

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.

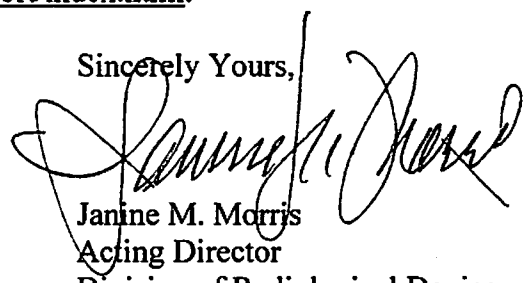
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's 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): K022069

Device name: OEC FluoroTrak 9800 Plus

Indications for use: The OEC FluoroTrak 9800 Plus Mobile Imaging System provides the physician with fluoroscopic imaging during diagnostic, surgical and interventional procedures. The Fluorotrak 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.

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

Concurrence of CDRH Office of Device Evaluation (ODE)

David G. Hegarty

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K022069

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

(Optional Format 1-2-96)