K021049

APR 17 2002

GE Medical Systems
OEC

GE OEC Medical Systems, Inc.
General Electric Company
384 Wright Brothers Drive, Salt Lake City, UT 84116-2862
http://www.gemedicalsystems.com

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:

March 25, 2002

Name of Submitter:

GE OEC Medical Systems, Inc.
384 Wright Brothers Drive
Salt Lake City, UT 84116
801-328-9300

Corresponding Official:

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

Device Proprietary Name:

OEC 9800 Plus Digital Mobile Imaging System

Classification Name:

System, X-ray, Fluoroscopic, Image-Intensified - or
System, X-ray, Mobile

Common/Usual Names:

Mobile C-arm,
Fluoroscopic Imaging System

Substantial Equivalence:

The *OEC 9800 Plus* is substantially equivalent to the following device that is currently marketed:

- GE OEC Medical Systems – OEC 9800 Digital Mobile Imaging System

These devices are mobile C-arm type x-ray systems intended for fluoroscopic imaging. The systems each include a high-voltage x-ray generator and control, x-ray tube, image intensifier, video image displays, digital image processing and image storage capability, as well as conventional spot-film capability.

Device Description:

Indications For Use

The *OEC 9800 Plus* is designed to provide fluoroscopic and spot-film imaging of the patient during diagnostic, surgical and interventional procedures. Clinical applications may include cholangiography, endoscopic, urologic, orthopedic, neurologic, vascular, cardiac, critical care and emergency room procedures. The system may be used for other imaging applications at the physician's discretion.

User Characteristics

The device is used by health care professionals such as physicians, surgeons, cardiologists, radiologists and technologists in hospitals, outpatient clinics and other clinical environments. It is expected that the device will be used on a daily basis. Users are trained by GE OEC applications specialists and/or qualified site personnel in the proper use of the device. The device labeling stipulates that only properly trained persons operate this equipment.

General Description

The *OEC 9800 Plus* is comprised of two mobile units: a C-arm stand and a workstation. The C-arm stand supports the high-voltage generator, x-ray controls, and a "C" shaped apparatus, which supports the x-ray tube on one end and an image intensifier on the other. 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 mobile workstation, supports image display monitors, image processing and recording devices.

Interfaces are provided for optional peripheral devices such as thermal or laser printers and VCRs. Video outputs are compatible with RS-170 format for domestic markets, CCIR format for international markets, and DICOM 3.0. An auxiliary connection is provided for a Medrad angiographic injector system to facilitate synchronized acquisition of angiographic images during contrast media injection.

Standards:

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

- Federal Performance Standard for Diagnostic X-ray Systems (21 CFR 1020.30-32)
- 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, General Requirements for Safety, Electromagnetic Compatibility
- IEC 60601-1-3,
  Medical Electrical Equipment, Radiation Protection in Diagnostic X-ray Equipment
- IEC 60601-2-7,
  Medical Electrical Equipment, Safety of HV/X-ray Generators
- 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.

Bill Gislason

Bill Gislason, Vice President, Quality Assurance, Regulatory, and Reliability
GE OEC Medical Systems, Inc.

WAG/dh

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: K021049
Trade/Device Name: OEC 9800 Plus Digital Mobile Imaging System
Regulation Number: 21 CFR 892.1650
Regulation Name: Image-intensified fluoroscopic x-ray system
Regulatory Class: II
Product Code: OWB, JAA and OXO
Dated: March 25, 2002
Received: April 1, 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):

Device name: OEC 9800 Plus Digital Mobile Imaging System

Indications for use: The OEC 9800 Plus Digital Mobile Imaging System is designed to provide fluoroscopic and spot-film imaging of the patient during diagnostic, surgical and interventional procedures. Examples of clinical applications may include cholangiography, endoscopic, urologic, orthopedic, neurologic, vascular, cardiac, 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 _____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)

Nancy C Brogdon
(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K021049