MAR 2 0 2003

510(k) Summary K024012

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:

November 27, 2002

Name of Submitter:

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

Corresponding Official:

Jeff Wagner,
Manager, Regulatory Affairs

Device Proprietary Name:

OEC 9800 E/CV+ 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 E/CV+ is substantially equivalent to the following devices that are currently marketed:

- GE OEC Medical Systems – OEC 9800 Plus Mobile Digital Imaging System
- Siemens Medical Solutions – Powermobil

These devices are mobile C-arm type x-ray systems intended for fluoroscopic imaging. The systems all include a high-voltage x-ray generator and control, rotating anode 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 E/CV+ is designed to provide fluoroscopic and spot-film imaging of the patient during diagnostic, surgical and interventional procedures. The system includes features specifically designed for use in diagnostic and interventional cardiac imaging procedures, and is also intended for cholangiography, endoscopic, urologic, orthopedic, neurologic, vascular, critical care and emergency room procedures. It 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, out-patient clinics and other clinical environments. It is expected that the device will be used on a daily basis. Users are trained in the proper use of the device by GE OEC applications specialists and/or qualified site personnel. The device labeling stipulates that only properly trained persons operate this equipment.

General Description

The OEC 9800 E/CV+ 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 an 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 E/CV+ 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 60601-1-4,
  General requirements for safety, Programmable electrical medical systems.
- 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
- IEC 60601-2-43
  Particular requirements for safety of X-ray equipment for interventional procedures.
- 93/42/EEC - Annex 1
  Essential Requirements of the Medical Devices Directive

Conclusion:

The OEC 9800 E/CV+ does not raise new questions of safety and effectiveness and is substantially equivalent to current legally marketed devices.

This concludes this 510(k) summary.

Jeff Wagner,
Manger, Regulatory Affairs
GE OEC Medical Systems, Inc.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 2 0 2003

Mr. Jeff Wagner
Manager, Regulatory Affairs
GE OEC Medical Systems, Inc.
General Electric Company
384 Wright Brothers Drive
SALT LAKE CITY UT 84116-2862

Re: K024012
Trade/Device Name: OEC 9800 E/CV$^+$
Digital Mobil Imaging System
Regulation Number: 21 CFR 892.1650
Regulation Name: Image intensified fluoroscopic x-ray system
Regulation Number: 21 CFR 892.1720
Regulation Name: Mobil x-ray system
Regulatory Class: II
Product Code: 90 JAA and IZL
Dated: February 28, 2003
Received: March 3, 2003

Dear Mr. Wagner:

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 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 Office of Compliance at one of the following numbers, based on the regulation number at the top of the letter:

8xx.1xxx	(301) 594-4591
876.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4616
884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx	(301) 594-4616
892.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4654
Other	(301) 594-4692

Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97) you may obtain. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.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

Indications For Use Statement

Applicant: GE OEC Medical Systems, Inc.

510(k) No. (if known): K024012

Device name: OEC 9800 E/CV+ Digital Mobile Imaging System

Indications for use: The OEC 9800 E/CV+ Digital Mobile Imaging System is designed to provide fluoroscopic and spot-film imaging of the patient during diagnostic, surgical and interventional procedures. It includes features designed specifically for diagnostic and interventional cardiac imaging procedures, and is also intended for use in cholangiography, endoscopic, urologic, orthopedic, neurologic, vascular, critical care and emergency room procedures. It may also 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 K024012