K041937

AUG 18 2004

## 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.

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|---|---|
| Date: | July 14, 2004 |
| Name of Submitter: | GE OEC Medical Systems, Inc.<br>384 Wright Brothers Drive<br>Salt Lake City, UT 84116<br>801-536-4668 |
| Corresponding Official: | Jeff Wagner<br>Manager, Regulatory Affairs |
| Device Proprietary Name: | OEC Olympus Mobile Fluoroscopy System |
| Classification Name: | Image Intensified Fluoroscopic X-ray System with Image Processing System |
| Common/Usual Names: | Fluoroscopic Imaging System |
| Substantial Equivalence: | The OEC Olympus Mobile Fluoroscopy System is substantially equivalent to the: |

- OEC 9800 Plus Digital Mobile Imaging System (K021049) marketed by GE OEC Medical Systems, Inc.
- OEC 9800 E/CV+ Digital Mobile Systems (K024012) marketed by GE OEC Medical Systems, Inc.

## Indications for Use

The OEC Olympus 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, vascular, cardiac, critical-care and emergency room procedures. The system may be used for other imaging applications at the physicians discretion.

## General Description

The OEC Olympus Mobile Fluoroscopy 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.

Interfaces are provided for optional peripheral devices such as thermal or laser printers and VCR's. 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 angiographic injector system to facilitate synchronization of angiographic images during contrast media injections.

Product Standards

The OEC Olympus Mobile Fluoroscopy System is designed in accordance with product safety and performance requirements established in the following standards:

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| 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 60601 | 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.

Jeff Wagner
Manager, Regulatory Affairs

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 18 2004

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: K041932
Trade/Device Name: OEC Olymups Mobile Fluoroscopy System
Regulation Number: 21 CFR 892.1650
Regulation Name: Image-intensified fluoroscopic x-ray system
Regulation Number: 21 CFR 892.1720
Regulation Name: Mobile x-ray system
Regulatory Class: II
Product Code: 90 JAA and IZL
Dated: July 14, 2004
Received: July 19, 2004

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 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 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):

Device name: OEC Olympus Mobile Fluoroscopy System

Indications for use: The OEC Olympus 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, vascular, cardiac, critical-care and emergency room procedures. 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)

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Concurrence of CDRH Office of Device Evaluation (ODE)

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

(Optional Format 1-2-96)

David G. Hoyum

**(Division Sign-Off)**
**Division of Reproductive, Abdominal,**
**and Radiological Devices**
**510(k) Number** K041932