JUL 7 - 2005

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 2, 2005
Name of Submitter:	GE OEC Medical Systems, Inc. 384 Wright Brothers Drive Salt Lake City, UT 84116 801-536-4517 (F) 801-328-4300
Corresponding Official:	Susan Schmidt Engineer - Safety & Regulatory
Device Proprietary Name:	GE OEC Everview 7500
Classification Name:	Image Intensified Fluoroscopic X-ray System with Image Processing System / Mobile C-arm.
Common/Usual Names:	Fluoroscopic Imaging System or Mobile C-arm.
Substantial Equivalence:	The OEC Everview Mobile Digital C-Arm is substantially equivalent to the:

- OEC Compact 7700 Mobile C-Arm (K000221) marketed by GE OEC Medical Systems, Inc.
- Flexiview 8800 Digital Mobile Imaging System (K003837/A) marketed by GE OEC Medical Systems, Inc.

Indications for Use

The OEC Everview 7500 is a mobile digital C-arm designed to provide fluoroscopic and spot-film images of the patient during diagnostic, surgical, critical-care and emergency room procedures. Examples of clinical application may include, but are not limited to cholangiography, endoscopy, urology, vascular, orthopedic, neurology and cardiac procedures. It is anticipated that this product will be used on a daily basis by such users, as prescribed by the physician. The system may be used for other imaging applications at the physician's discretion.

General Description

The OEC Everview 7500 is an image intensified fluoroscopic mobile C-arm system. It consists of a C-arm that supports a high-voltage generator, x-ray tube, x-ray controls, image intensifier, and CRT monitors. It 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, and supports image processing and recording devices.

Interfaces are provided for optional peripheral devices such as thermal printer and monitors. Video outputs are compatible with CCIR format for international markets.

Product Standards

The OEC Everview 7500 is designed in accordance with product safety and performance requirements established in the following standards:

Document	Description
Title 21 CFR, Subchapter J, Parts 807, 1020.30 through 1020.32	U.S. requirements for 510(k) submissions, U.S. Federal Performance Standard for Diagnostic X-ray Systems, U.S.
Canadian Food & Drug Act SOR/98-292 7 May 2004	Health Canada- Canadian Medical Device Regulation
ANSI/NFPA 70 and 99	US National Electric Code/Electrical Equipment, Health Care Facilities
UL 60601-1: 2003: 1st Edition	Medical Electrical Equipment, Part 1: General Requirements for Safety including any Collateral Std (601-1-x) and Particular Std (601-2-x), as adopted.
CSA-C22.2 No. 601.1-M90	Medical Electrical Equipment, Part 1: General Requirements for Safety including any Collateral Std (601.1.x) and Particular Std (601.2.x), as adopted.
EN 60601-1 (IEC 60601-1:1988 + A1 & A2)	Medical Electrical Equipment, Part 1: General Requirements for Safety
IEC 60601-1-1:2000: 2nd edition	Collateral Std: Safety of Medical Electrical Systems
IEC 60601-1-2:2001: 2nd edition	Collateral Std: Electromagnetic Compatibility
IEC 60601-1-3:1994: 1st edition	Collateral Std: Radiation Protection in Diagnostic X-ray Equipment
IEC 60601-1-4:2000: 1.1 edition (+A1)	Collateral Std: Safety of Programmable Medical Systems
IEC 60601-2-7:1998: 2nd edition	Particular Std: Safety of H.V. Diagnostic X-ray Generators
IEC 60601-2-28:1993: 1st edition	Particular Std: Safety of X-ray Tube and X-ray Source Assemblies
IEC 60601-2-32:1994: 1st edition	Particular Std: Safety of Associated Equipment of X-ray Equipment
93/42/EEC, Annex I (Essential Requirements)	Council Directive Concerning Medical Devices (European Union)

This concludes this 510(k) Summary.

GE OEC MEDICAL SYSTEMS, INC.

Susan Schmidt

Susan Schmidt,
Engineer- Safety & Regulatory

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 7 - 2005

Ms. Susan Schmidt
Engineer – Safety & Regulatory
GE OEC Medical Systems, Inc.
384 Wright Brothers Drive
SALT LAKE CITY UT 84116

Re: K051490
Trade/Device Name: OEC Everview 7500
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: JAA & IZL
Dated: June 2, 2005
Received: June 6, 2005

Dear Ms. Schmidt:

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 (Premarket Approval), 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 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" (21 CFR 807.97). 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) 443-6597 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

Indications For Use Statement

Applicant: GE OEC Medical Systems, Inc.

510(k) No. (if known): K051490

Device name: OEC Everview 7500

Indications for use: The OEC Everview 7500 is a mobile digital C-arm designed to provide fluoroscopic and spot-film images of the patient during diagnostic, surgical, critical-care and emergency room procedures. Examples of clinical application may include, but are not limited to cholangiography, endoscopy, urology, vascular, orthopedic, neurology and cardiac procedures. It is anticipated that this product will be used on a daily basis by such users, as prescribed by the physician. 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 K051490