OEC MEDICAL SYSTEMS, INC

384 WRIGHT BROTHERS DRIVE

SALT LAKE CITY, UTAH 84116

801 328-9300
FAX 801 328-4300

K974355

FEB 17 1998

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:

November 14, 1997

Name of Submitter:

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

Corresponding Official:

Ted L. Parrot,
Vice President, Quality/Regulatory Affairs.

Device Proprietary Name:

Interventional Mobile Digital Imaging System (herein called *IMDIS*)

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 *IMDIS* is substantially equivalent to the following devices which are currently marketed:

- OEC Medical Systems - SERIES 9600® Mobile Digital Imaging System
- Philips Medical Systems - BV 300 Series Mobile C-arm System

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, 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 *IMDIS* is designed to provide fluoroscopic and spot-film imaging of the patient during diagnostic, surgical and interventional procedures. Clinical applications may include, but are not limited to, 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, out-patient clinics and other clinical environments. It is expected that the device will be used on a daily basis. Users are trained by 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 *IMDIS* 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 which 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 *IMDIS* 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 601-1,
  Medical Electrical Equipment, General Requirements for Safety
- IEC 601-1-2,
  Medical Electrical Equipment, General Requirements for Safety, Electromagnetic Compatibility
- IEC 601-1-3,
  Medical Electrical Equipment, Radiation Protection in Diagnostic X-ray Equipment
- IEC 601-2-7,
  Medical Electrical Equipment, Safety of HV/X-ray Generators
- IEC 601-2-32,
  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.

Ted L. Parrot,
Vice President, Quality Assurance/Regulatory Affairs
OEC Medical Systems, Inc.

TLP/jw

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 17 1998

Ted L. Parrot
Vice President, Quality Assurance/
Regulatory Affairs and Official Correspondent
OEC Medical Systems, Inc.
384 Wright Brothers Drive
Salt Lake City, Utah 84116

Re: K974355
Interventional Mobile Digital Imaging System
Dated: November 14, 1997
Received: November 19, 1997
Regulatory class: II
21 CFR 892.1650/Procode: 90 JAA
21 CFR 892.1720/Procode: 90 IZL

Dear Mr. Parrott:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to 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). 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 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 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 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4613. 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" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

Lillian Yin, Ph.D.
Director, Division of Reproductive,
Abdominal, Ear, Nose and Throat,
and Radiological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications For Use Statement

Applicant: OEC Medical Systems, Inc.

510(k) No. (if known): K974355

Device name: Interventional Mobile Digital Imaging System (*IMDIS*)

Indications for use: The *IMDIS* is designed to provide fluoroscopic and spot-film imaging of the patient during diagnostic, surgical and interventional procedures. Clinical applications may include, but are not limited to, 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)

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT, and Radiological Devices
510(k) Number K974355