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K992506

OEC MEDICAL SYSTEMS, INC

384 WRIGHT BROTHERS DRIVE

SALT LAKE CITY, UTAH 84116

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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:

July 23, 1999

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 Assurance & Regulatory Affairs.

Device Proprietary Name:

MINI 6800 Digital Mobile C-arm

Classification Name:

Mobile X-ray System

Common/Usual Names:

Mini C-arm
Mobile C-arm

Substantial Equivalence:

The MINI 6800 Digital Mobile C-arm is substantially equivalent to the following devices that are currently marketed:

- MINI 6600 Digital Mobile C-arm
- FluoroScan Premier
- ORCA Orthopedic C-arm

All of these devices are mobile C-arm type diagnostic x-ray systems intended for fluoroscopic imaging, particularly during orthopedic procedures and extremity examinations. All systems include a high-voltage x-ray generator, stationary anode x-ray tube, image intensifier, video image display, digital image processing and image storage capability.

Device Description:

Indications for Use

The MINI 6800 Digital Mobile C-arm is designed to provide the physician with general fluoroscopic visualization of the patient including but not limited to surgical orthopedic and extremity imaging. The device is not intended for whole-body pediatric imaging.

User Characteristics

The device is used by health care professionals such as medical doctors, surgeons, radiologists and technologists in a hospital or clinical environment. In addition to being qualified within their respective medical fields, users must be trained in the use of medical x-ray equipment. OEC applications specialists train the user in the proper use of this product. The device labeling stipulates that only properly trained persons operate this equipment.

General Description

The OEC mobile workstation, which supports image display monitors, image processing and recording devices, is combined with a miniature C-arm to create the MINI 6800 Digital Mobile C-arm.

Interfaces are provided for optional peripheral devices such as thermal or laser printers and VCRs. Video outputs are compatible with RS-170 format for North American markets, CCIR format for international markets, and DICOM 3.0.

The MINI 6800 has the following physical characteristics:

- All components are contained in one mobile workstation.
- An articulating arm is attached to the workstation and extends out from the main cabinet to position the x-ray imaging components.
- All mechanical positioning of the workstation and articulating arm is manual (non-motorized).
- The system is powered by a non-detachable power cord.
- Power ratings between 100–240 VAC, 4–6 Amps at 50/60 Hz.
- Internal system power is insulated from input power by an isolation transformer.
- Fluoroscopic operation:

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-- 40 to 80 kVp

-- 20 to 160 μA (0.020 to 0.160 mA)

-- Automatic Exposure Rate Control

Major components of the system include:

- Dual video monitors
- Input isolation transformer
- Digital image processing and x-ray control
- Monoblock X-ray tube and high-voltage power supply
- Image intensifier

Standards:

The MINI 6800 Digital Mobile C-arm is designed in accordance with product safety requirements established in the following standards:

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 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, 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, Safety of HV/X-ray Generators
IEC 60601-2-28	Medical Electrical Equipment, X-ray Tubes and X-ray 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.

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

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

Mr. Ted L. Parrot
Vice President, Quality Assurance & Regulatory Affairs
OEC Medical Systems, Inc.
384 Wright Brothers Drive
SALT LAKE CITY UT 84116

NOV 17 2011

Re: K992506
Trade/Device Name: Mini 6800 Digital Mobile C-Arm
Regulation Number: 21 CFR 892.1650
Regulation Name: Image intensified fluoroscopic x-ray system, mobile
Regulatory Class: II
Product Code: OXO
Dated: July 23, 1999
Received: July 27, 1999

Dear Mr. Parrot:

This letter corrects our substantially equivalent letter of August 19, 1999.

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 (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. Please Note: CDRH does not evaluate information related to contact liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

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); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 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/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely Yours,

Mary S. Pastel, Sc.D.
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: OEC Medical Systems, Inc.

510(k) No. (if known):

Device name: MINI 6800 Digital Mobile C-arm

Indications for use: The MINI 6800 Digital Mobile C-arm is designed to provide the physician with general fluoroscopic visualization of the patient including but not limited to surgical orthopedic and extremity imaging. The device is not intended for whole-body pediatric imaging.

(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 K992506