JAN 21 1993
K926056

# 510(k) SUMMARY

**Date:** November 25, 1992

**Name of Submitter:** OEC-Diasonics Inc.
384 Wright Brothers Drive
Salt Lake City, UT. 84116
(801)328-9300

**Corresponding Official:** Thomas R. Meyers,
Dir. of Quality/Regulatory Affairs.

**Device Proprietary Name:** 9600

**Classification Name:** System, X-ray, Fluoroscopic, Image-Intensified, with Spot Film capability

**Common/Usual Name:** Fluoroscopic Imaging/C-Arm System

**Substantial Equivalence:** The OEC-Diasonics 9600 is substantially equivalent to the systems listed below.

Systems which are currently marketed:

(1) Philips BV-29 Mobile C-Arm System.
(2) GE Stenoscop D6/D9 Mobile C-Arm System.
(3) Amerisys (Ziehm) ARIS C20Mobile C-Arm System.
(4) Siemens Siremobil 2000 Mobile C-Arm System.
(5) Toshiba SXT-650A Mobile C-Arm System.
(6) Fischer Omni 325 Mobile C-Arm System.
(7) OEC-Diasonics Series 9000 Mobile C-Arm System.

**Similarities and Differences:** Refer to the attached *9600 Similarities/Differences Comparison Matrix* charts. The chart compares the functional characteristics of the 9600 with (7) similar post-amendment devices which are currently available.



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**Intended Use:** The 9600 is designed to provide the physician with both fluoroscopic and radiographic (spot film) visualization of the patient. It can be used in surgical orthopedic, critical care, and emergency procedures, as well as cardiac and neurological applications. References made in this 510(k) summary to the radiographic mode apply to the use of a spot film device only.

**Device Description:** The 9600 is comprised of a C-Arm and a Monitor Cart. The C-Arm is a single plane fluoroscopy system mounted on wheels with a curved arm that supports an X-ray tube on one end and a 9"/6"/4" tri-mode image intensifier on the other. The "C" is constructed to provide a variety of positions for optimal patient imaging including an AP to Lateral of 90°. The Monitor Cart supports the image display as well as the image processing functions. It also contains such options as video tape recorders and hard copy cameras. Pulsed fluoroscopy is standard.

The overall system design of the 9600 is substantially the same as the OEC-Diasonics Series 9000 C-arm products except for the following changes:

(1) Improved mobility and maneuverability.
(2) Reduction in size and weight.
(3) Improved ease of cleaning and serviceability.
(4) Update to current technology and replace antiquated parts.

The 9600 uses the same type of x-ray imaging technology as the products currently marketed by OEC-Diasonics.

**Product Safety Standards:** In addition to complying with the Federal Performance Standard for Diagnostic X-ray Systems (21 CFR 1020.30-32), the 9600 is designed in accordance with guidelines established in the following safety standards:

| | |
|---|---|
| UL 478, | Standard for Electronic Data-Processing Equipment (4th Edition) |
| UL 187, | Standard for X-ray Equipment |
| IEC 601-1, | Medical Electrical Equipment, General Requirements for Safety |
| IEC 601-2-7, | Medical Electrical Equipment, Safety of HV/X-ray Generators |
| CSA-C22.2 No.601.1-M90, | Medical Electrical Equipment |
| NFPA 99, | Standard for Health Care Facilities |
| NFPA 70, | National Electrical Code |
| IEC 601-1-2, | Medical Electrical Equipment, General Requirements for Safety, Electromagnetic Compatibility |

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

JAN 11 2012

Mr. Thomas R. Meyers
Director of Quality and
Regulatory Affairs
OEC – Diasonics, Incorporated
384 Wright Brothers Drive
SALT LAKE CITY UT 84116

Re: K926056
Trade/Device Name: 9600 C-Arm Mobile Fluoroscopic
X-Ray System
Regulation Number: 21 CFR 892.1650
Regulation Name: Image-intensified Fluoroscopic x-ray system
Regulatory Class: II
Product Code: OXO
Dated: November 25, 1992
Received: December 1, 1992

Dear Mr. Meyers:

This letter corrects our substantially equivalent letter of January 21, 1993.

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

Dear Mobile Fluoroscopic Device Manufacture:

This letter is to advise you that the FDA is in the process of updating the Product Codes for Mobile Fluoroscopic (OXO) devices to provide greater specificity regarding Mobile X-Ray devices. Product Codes, and their definitions, can be found in our classification database (http"//www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpcd/classification.cfm).

Mobile X-Ray devices have expanded greatly in scope since the creation of the first Mobile X-Ray devices product code, IZL, over 30 years ago: from standard mobile radiographic systems to sophisticated mobile interventional fluoroscopy devices. Because of the variety of mobile X-Ray devices currently on the market, the new product code will allow FDA to distinguish between the different types of mobile S-Ray devices marketed in the United States (U.S.), thereby allowing us to serve the Medical Imaging device industry and other stakeholders in a more clear and efficient manner.

**What you should do at this time:**

When preparing import paperwork, including your FDA Listing, **you must** continue to reference the "Current Product Codes" that are found on your 510(k) letter of substantial equivalence to avoid delays at the port of entry into the U.S. Do **not** use the "Planned Common Name and Planned Product Code" on any FDA Submission until the codes have been finalized for your device, and you have been **notified by FDA by receipt of a revised letter of substantial equivalence for your 510(k)(s). (Attached)**

**Need Further Clarifications?**

If you need further clarification on the issue or any other type of assistance in complying with FDA regulations, please contact the Division of Small Manufactures, International and Consumer Assistance, (DSMICA), by email at DSMICA@CDRH.FDA.GOV

John Stigi
Director
Division of Small Manufactures, International and Consumer Assistance
Office of Communication, Education and Radiation Programs
Center for Devices and Radiological Health
U.S. Food and Drug Administration