



384 WRIGHT
BROTHERS DRIVE

SALT LAKE CITY,
UTAH 84116

801-328-9300
FAX 801-328-4300

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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:

September 27, 1996

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:

Series 9600 Mobile Digital Imaging System (modified - Phase III)

Classification Name:

System, X-ray, Fluoroscopic, Image-Intensified

Common/Usual Names:

Fluoroscopic Imaging System
Mobile C-arm

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Substantial Equivalence:

The modified Series 9600 Mobile Digital Imaging System is substantially equivalent to the following systems which are currently marketed:

- OEC Medical Systems - Series 9600 Mobile Digital Imaging System [original 510(k) device]
- Philips Medical Systems - BV 29 Mobile Imaging System
- Philips Medical Systems - BV 212 Mobile Imaging System

All of these devices are mobile C-arm type diagnostic x-ray systems intended for fluoroscopic imaging. The systems all include a high-voltage x-ray generator, x-ray tube, image intensifier, video image displays, digital image processing and image storage capability.

Device Description:

Indications For Use

The Series 9600 Mobile Digital Imaging System 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. The device is used in hospitals, out-patient clinics and other clinical environments to provide fluoroscopic and spot-film imaging during diagnostic, surgical and interventional procedures. 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 Series 9600 system is comprised of two mobile units: the C-arm unit supports the high-voltage generator, x-ray components and x-ray controls; and the other unit, a mobile workstation, supports image display monitors, image processing and recording devices. The C-arm includes a "C" shaped arm that 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.

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.

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Standards:

In addition to complying with the Federal Performance Standard for Diagnostic X-ray Systems (21 CFR §1020.30-32), the modified Series 9600 Mobile Digital Imaging System is designed in accordance with guidelines established in the following standards:

ANSI/NFPA 99,
Standard for Health Care Facilities

ANSI/NFPA 70,
National Electrical Code

UL 187,
Standard for X-ray Equipment

CSA-C22.2 No.601.1-M90,
Medical Electrical Equipment

IEC 601-1,
Medical Electrical Equipment, General Requirements for Safety

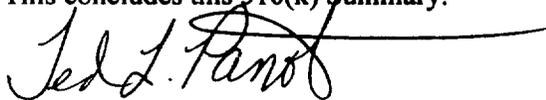
IEC 601-1-2,
Medical Electrical Equipment, General Requirements for Safety, Electromagnetic Compatibility

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

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.