K993687

DEC 21 1999

OEC MEDICAL SYSTEMS, INC

384 WRIGHT BROTHERS DRIVE

SALT LAKE CITY, UTAH 84116

801-328-9300
FAX 801-328-4300

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:	October 25, 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:	UroView 2800
Classification Name:	Image Intensified Fluoroscopic X-ray System
Common/Usual Names:	Fluoroscopic Imaging System Urology Table
Substantial Equivalence:	The UroView 2800 is substantially equivalent to the following devices that are currently marketed: • OEC UroView 2600 (K940295) • Liebel-Flarsheim Hydradjust IV (K943581) • Liebel-Flarsheim HydraVision (K904145)

Device Description:

General Description

The UroView 2800 is a fluoroscopic x-ray system including a tilting patient-support table with overhead x-ray tube assembly, high-voltage x-ray generator, image intensifier, and video image display. A separate mobile workstation provides digital image processing, image storage capability, and additional video display.

Indications for Use

The UroView 2800 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 urologic and endoscopic 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 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.

Standards:

The UroView 2800 is designed in accordance with product safety and performance 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
IEC 60601-2-46	Medical Electrical Equipment, Safety of Operating Tables
93/42/EEC - Annex 1	Essential Requirements of the Medical Devices Directive

This concludes this 510(k) Summary.

OEC MEDICAL SYSTEMS, INC.

Ted L. Parrot,
Vice President, Quality Assurance & Regulatory Affairs

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 21 1999

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: K993687
UroView 2800
Dated: October 25, 1999
Received: November 1, 1999
Regulatory class: II
21 CFR 892.1650/Procode: 90 JAA
21 CFR 876.4890/Procode: 78 KQS

Dear Mr. Parrot:

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 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). 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 requirements, 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/dsma/dsmamain.html".

Sincerely yours,

CAPT Daniel G. Schultz, M.D.
Acting 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):

Device name: UroView 2800

Indications for use: The UroView 2800 is designed to provide fluoroscopic and spot-film imaging of the patient during diagnostic, surgical, and interventional procedures. Clinical applications include but are not limited to urologic and endoscopic 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 K993687