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510(K) SUMMARY
ER150/M2

K021456

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I. **Submitter**:

WORLD OF MEDICINE Lemke GmbH
Danziger Strasse 21
82194 Gröbenzell
Germany

II. **Device Names:**

1.	Classification Name:	Accessory to an Endoscope
2.	Common or Usual Name:	Medical Monitor
3.	Proprietary Name:	ER150/M2

III. **Classification:**

The proposed device is classified as class II according to 21 C.F.R. § 876.1500. The product code for the device is GCJ.

IV. **Predicate Devices:**

- **Sony Trinitron Color Video Monitor PVM-1343 MD** (K885042) manufactured by Sony Medical Electronics, Co.

V. **Intended Use:**

The ER150/M2 is a video monitor intended to display viewable images transmitted by standard video signals during surgical or diagnostic procedures, particularly in endoscopy.

VI. **Device Description:**

The ER150/M2 is a color video monitor intended to display viewable medical images transmitted by standard video signals. In particular, the device is intended for use as part of a visualisation system in endoscopic surgery. The monitor accepts and processes composite=FBAS, Y-UV, analog RGB, digital RGB, Y/C signals and NTSC, PAL and SECAM standard video signals. The ER150/M2 is designed with a digital microprocessor and offers an automatic input selection. The received signal is displayed on a 20" screen. The images can be adjusted by the user for color, contrast, hue, brightness, enhanced sharpness and color temperature (6500K or 9300K). Additional output sockets of the ER150/M2 allow the connection to further equipment including a second monitor or recording device.

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VII. Performance Standards:

The ER150/M2 meets the requirements of the performance standard 21 C.F.R. §1020.10.

VIII. Voluntary Standards:

The medical monitor ER150/M2 complies with the International Standard IEC 60601-1, IEC 60601-1-2 and conforms to the Medical Device Directive 93/42/EEC. In addition, the ER150/M2 meets the requirements of the Underwriters Laboratories standard UL2601-1.

VIII. Substantial Equivalence:

The medical monitor ER150/M2 described in this notification is similar in intended use, design and technological characteristics to the **Sony Trinitron Color Video Monitor PVM-1343 MD** (K885042) manufactured by Sony Medical Electronics, Co.

Both the ER150/M2 and the predicate device are intended to display viewable medical images containing information on surgical or diagnostic procedures including video signals gernerated by endoscopic video equipment. The differences between the ER150/M2 and the predicate device are limited to picture quality and handling convenience and do not raise new questions of safety and effectiveness.

Accordingly, WORLD OF MEDICINE Lemke GmbH believes that the medical monitor ER150/M2 is substantially equivalent to the predicate device which received clearance from FDA on December 22, 1988 (K885042).

Signed: S. Raab

Susanne Raab
Official Correspondent

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

World of Medicine Lemke GmbH
c/o Mrs. Susanne Raab
91 Trowbridge Street, #21
Cambridge, MA 02138

AUG 01 2002

Re: K021456
Trade/Device Name: ER 159/M2 Medical Video Monitor
Regulation Number: 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: II
Product Code: GCJ
Dated: April 23, 2002
Received: May 6, 2002

Dear Mrs. Raab:

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 application (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.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), 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 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); 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.

This letter will allow you to begin marketing your device as described in your Section 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 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. 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" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer 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,

for Mark N Melkerson

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

STATEMENT OF INDICATIONS FOR USE

APPLICANT: WORLD OF MEDICINE Lemke GmbH

510(K) NUMBER (if known): K021456

DEVICE NAME: ER150/M2

INDICATIONS FOR USE:

The ER150/M2 is a color video monitor intended to display viewable images transmitted by standard video signals during surgical or diagnostic procedures, particularly in endoscopy.

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Per 21 C.F.R. § 801.109)

(Optional Format 1-2-96)

for Mark N Milhoan

(Division Sign-Off)
Division of General [illegible]rative
and Neurological D[illegible]

510(k) Number K021456