AUG 2 0 2002

K021717

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510(K) SUMMARY
Endoscopic Light Source XL300/L5

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:	Endoscopic Light Source
3.	Proprietary Name:	Endoscopic Light Source XL300/L5

III. **Classification**:

Class II. This device is described in 21 C.F.R. § 876.1500. The product code for the device is GCT.

IV. **Predicate Device**:

- **Karl Storz Xenon 300 Light Source for Non-Flash Applications** (K962595) manufactured by Karl Storz Endoscopy-America, Inc.

V. **Intended Use:**

The Endoscopic Light Source XL300/L5 is intended to be used with fiber optic endoscopes to provide illumination of body cavities, hollow organs and canals during endoscopic procedures.

VI. **Device Description:**

The Endoscopic Light Source XL300/L5 uses a 300 W xenon lamp to provide illumination during endoscopic diagnostic and surgical procedures through a fiber optic cable, which is connected to the device. Brightness can be adjusted manually. The color temperature of the xenon lamp is approximately 5600 °K and the lamp life is approximately 500 hours.

VII. **Substantial Equivalence:**

The Endoscopic Light Source XL300/L5 described in this notification is similar in design and technological characteristics to the **Karl Storz Xenon 300 Light Source for Non-Flash Applications** (K962595) manufactured by Karl Storz Endoscopy-America, Inc.

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Both the Endoscopic Light Source XL300/L5 and the predicate device is intended to provide illumination of body cavities, hollow organs and canals during endoscopic diagnostic and surgical procedures. In addition, both devices are designed to be used with a 300 W Xenon lamp.

The differences between the Endoscopic Light Source XL300/L5 and predicate device are minor and raise no new questions of safety and effectiveness. Accordingly, WORLD OF MEDICINE Lemke GmbH believes that the Endoscopic Light Source XL300/L5 is substantially equivalent to the predicate device currently on the market.

VIII. Performance Data:

The Endoscopic Light Source XL300/L5 will comply with the International Standard IEC 60601-1, IEC 60601-1-2 and will conform to the Medical Device Directive 93/42/EEC. In addition, the device will meet the requirements of the Underwriters Laboratories Standard UL2601-1.

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

AUG 2 0 2002

WORLD OF MEDICINE LEMKE GmbH
c/o Ms. Susanne Raab
Official Correspondent
91 Trowbridge Street
CAMBRIDGE MA 02138

Re: K021717
Trade/Device Name: Endoscopic Light Source XL300/L5
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: II
Product Code: 78 GCT
Dated: May 11, 2002
Received: May 23, 2002

Dear Ms. 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 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 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), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

8xx.1xxx	(301) 594-4591
876.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4616
884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx	(301) 594-4616
892.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4654
Other	(301) 594-4692

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 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,

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological 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): K021717

DEVICE NAME: Endoscopic Light Source XL300/L5

INDICATIONS FOR USE:

The Endoscopic Light Source XL300/L5 is intended to be used with fiber optic endoscopes to provide illumination of body cavities, hollow organs and canals during endoscopic procedures.

(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)

Prescription Use ✓
(Per 21 CFR 801.109)

Nancy C. Brogdon
(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K021717