OCT 29 1997 K972984

510(k) Notification: Lerner Medical, Inc. Autoclavable 10MM Diagnostic Laparoscope

SUMMARY OF SAFETY AND EFFECTIVENESS
Lerner Medical, Inc. Autoclavable 10MM Laparoscope

1. Name and Address of Applicant

Lerner Medical, Inc.
840 West Main Street
Lansdale, PA 19446
Contact: Michael Pollack
President

2. Device Name and Classification

Product Nomenclature	Classification Number	Class	Regulation Number
Laparoscope, General and Plastic Surgery	78GCJ	II	21 CFR §876.1500
Laparoscope, Gynecological and Accessories	85HET	II	21 CFR §884.1720

Common/Usual Name:
Autoclavable Laparoscope

Trade/Proprietary Name:
Lerner Medical, Inc. Autoclavable 10MM

3. Identification of Predicate Devices

Marketed Devices Used for Substantial Equivalence:
The Lerner Medical, Inc. Autoclavable Laparoscope is substantially equivalent to autoclavable laparoscopes marketed after May 28, 1976 and were determined as substantially equivalent by the US FDA. The Lerner Medical, Inc. Autoclavable 10MM Laparoscope is substantially equivalent to the following device; the Cuda Products Corporation Autoclavable Laparoscope (510(k): K935818)

4. Device Description:

The Lerner Medical, Inc. Autoclavable 10MM Laparoscope System is a 10MM diameter laparoscope which may be used during diagnostic and operative laparoscopy procedures for visualization of the abdominal cavity. The laparoscope may be disinfected using high level disinfectants or sterilized using ethylene oxide gas or steam autoclave.

5. Intended Use of the Marketed Device:
The Lerner Medical, Inc. Autoclavable 10MM Laparoscope is intended to be used for visualization of the abdominal cavity during general and thoracic surgery.

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Mr. Michael Pollack
President
Lerner LMI Medical, Inc.
840 West Main Street
Lansdale, Pennsylvania 19446

OCT 29 1997

Re: K972984
Trade Name: Lerner Medical, Inc. Autoclavable 10 MM Laparoscope
Regulatory Class: II
Product Code: GCJ
Dated: August 4, 1997
Received: August 11, 1997

Dear Mr. Pollack:

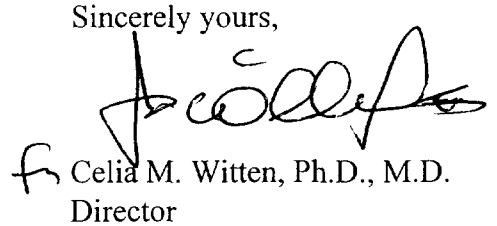
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of 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) 594-4595. 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/dsmamain.html".

Sincerely yours,



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

Enclosure

510(k) Number (if known):

Device Name: Lerner Medical, Inc. Autoclavable 10MM Laparoscope

Indications For Use:

General Surgery
- Laparoscopic cholecystectomy, Hernia repair, Appendectomy, Nissen fundal plication, Diagnosis and Management of acute abdomen

Thoracic Surgery
- Pericardiectomy, Pneumonectomy, Evaluation of pulmonary nodule, Biopsy, Pleurodesis

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K972984

Prescription Use X OR Over-The-Counter Use
(Per 21 CFR 801.109)

(Optional Format 1-2-96)