

OCT 21 1998

SUMMARY OF SAFETY AND EFFECTIVENESS

K 98 2013

- 1. Submitter's Information:** Dated: May 29, 1998
MGB Endoskopische Geräte GmbH Berlin
Rudower Chaussee
D-12489 Berlin

Contact Person: Bob Leiker, VP Regulatory Affairs
Medison America, Inc.
6616 Owens Drive
Pleasanton, CA 94588
- 2. Common or Usual Name:** Laparoscope, rigid telescope
Proprietary Name: MGB LAPALUX® Telescope
Classification Names: Laparoscope, 21 CFR 876.1500
Class II, Product Code: 78 GCJ
- 3. Predicate Device:** Karl Storz Hopkins II rigid autoclavable telescope. 510(k) number: K935279
- 4. Description of Device:** The MGB LAPALUX telescope is a laparoscope designed for general, gynecological and plastic surgery. It is similar in design to other telescopes currently available for commercial distribution in the United States.
- 5. Statement of intended use:** The MGB LAPALUX telescope is used to allow access and observation of body cavities during endoscopic procedures.
- 6. Statement of technological characteristics:** The MGB LAPALUX telescope has no significant differences in design, materials or other technological characteristics compared to the predicate device.

The intended use and the technological characteristics are the same as the predicate device and therefore we believe it is substantially equivalent to the predicate device.
- 7. Performance Standards:** Although there are no performance standards established by the FDA for these devices, the MGB LAPALUX telescope has been designed and manufactured to meet the following standards:
 - DIN 58140, part 1 & 2 (fiber optics)
 - DIN 58105, part 1, 12/86 (medical telescopes)
 - DIN 58141, part 1 - 3, 8/89 and part 4, 6/90 (fiber optics testing)
 - EN 1441 (risk analysis)
 - EU Directive 93/42/EWG, appendix I, 6/93 (Medical Device Directive)



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Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Mr. Bob Leiker
Vice President of Regulatory affairs
and Quality Assurance
c/o Medison America, Inc.
6616 Owens Dr.
Pleasanton, California 94588

Re: K982013
Trade Name: MGB LAPALUX® Telescope
Regulatory Class: II
Product Code: GCJ
Dated: September 18, 1998
Received: September 21, 1998

Dear Mr. Leiker:

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 requirement, 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

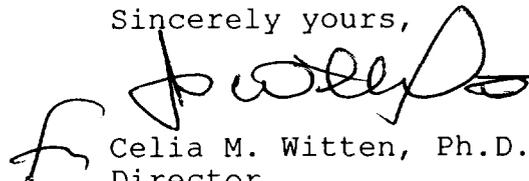
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Product Radiation Control provisions, or other Federal laws or regulations.

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) 594-4659. 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" (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,



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

TAB 1

510(k) Number: K982013

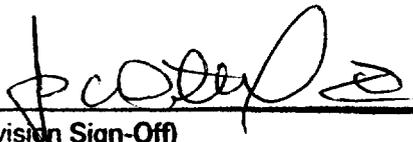
Device Name: MGB LAPALUX® Telescope

Indications for Use:

- For use to allow access and observation of body cavities during endoscopic and/or laproscopic procedures:
 - General endoscopic and laparoscopic surgical procedures.
 - Plastic, reconstructive, and aesthetic surgical procedures.
 - Thoracic cavity diagnostic and therapeutic procedures.
 - Athroscopy of body joints during diagnostic and therapeutic procedures.

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

Concurrence of CDRH, Office of Device Evaluation (ODR)



(Division Sign-Off)
Division of **General Restorative Devices**
510(k) Number K982013

Prescription Use (Per 21 CFR 801.109) ✓