

APPENDIX VII

510(k) SUMMARY

AUG - 6 1997

**510(k) NUMBER:** PENDING

**SUBMITTED BY:** Applied Medical Resources Corporation  
26051 Merit Circle, Unit# 103  
Laguna Hills, California 92653  
(714) 582-6120 EXT. 310

**CONTACT PERSON:** Howard V. Rowe

**DATE OF PREPARATION:** July 12, 1996

**NAME OF DEVICE:** Applied Medical Mini-Laparoscope.

**CLASSIFICATION NAME:** Endoscope

**TRADE NAME:** Not Determined

**SUMMARY STATEMENT:** The AMR Mini-laparoscope is designed and indicated for visualization of body cavities during laparoscopic procedures. The device features a stainless steel body containing light fibers encased in epoxy, an aluminum eyepiece, a light post for purposes of connecting a light source and a means of connecting to a video monitor. The AMR Mini-laparoscope is substantially equivalent to a device marketed by IMAGYN Corp. under the name of MICROLAP™ 2mm LAPAROSCOPE and INTRODUCER.

The design configuration of the AMR Mini-laparoscope is also similar to the AMR Rigid Ureteroscope which was previously approved under K901214.

Mechanical and biocompatibility tests were performed to verify functional and structural integrity and material safety of the Mini-laparoscope. All testing has demonstrated that the AMR Mini-laparoscope is comparable to the predicate devices and introduces no new safety and effectiveness issues when used as indicated.

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

AUG - 6 1997

Mr. Howard V. Rowe  
Regulatory Affairs Manager  
Applied Medical Resources  
26051 Merit Circle, Bldg. 104  
Laguna Hills, California 92653

Re: K962777  
Applied Medical@Mini Laparoscope  
Dated: June 30, 1997  
Received: July 9, 1997  
Regulatory class: II  
21 CFR §884.1720/Product code: 85 HET

Dear Mr. Rowe:

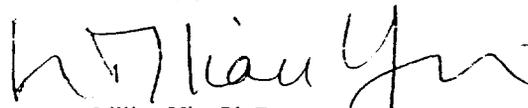
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of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

Sincerely yours,



Lillian Yin, Ph.D.  
Director, Division of Reproductive,  
Abdominal, Ear, Nose and Throat,  
and Radiological Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

APPENDIX IX

INDICATIONS FOR USE

Food and Drug Administration  
Center for Devices and  
Radiological Health  
Office of Device Evaluations (HFZ-401)  
9200 Corporate Boulevard  
Rockville, MD 20850

Applied Medical Resources is providing this separate cover page for the Applied Medical Mini-Laparoscope "Indication for Use" to reflect the revision made in the Supplement #1 labeling.

510(k) Number: K962777

Device Name: AMR Mini-Laparoscope.

Indications for Use: The AMR Mini-Laparoscope is indicated for visualization and accessing the abdomen during laparoscopic procedures such as (but not limited to):

- Unexplained pelvic pain
- Infertility Work-up
- Tubal sterilization
- Diagnosis and/or treatment of ectopic pregnancy
- Evaluation, diagnosis and/or treatment of pelvic tumors, including myomata (less than 16 weeks gestational size.)
- Evaluation of congenital anomalies of the pelvic organs
- Retrieval of foreign bodies
- Determination of the presence and extent of pelvic endometriosis
- Determination of the presence and extent of pelvic inflammatory disease (if not in acute stage)
- Access to abdomen for surgical procedures such as LAVH
- Visualization, diagnosis and/or treatment of perforate abdominal (pelvic) organs.

Signature: [Signature] Title: DIRECTOR  
REGULATORY AFFAIRS Date: 5/8/97

(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 Use   
(Per 21 CFR 801.109)

Colin M. Pollard (Optional Format -2-96)  
(Division Sign-Off)

Division of Reproductive, Abdominal, ENT,  
and Radiological Devices

510(k) Number K962777