K973891
1 of 1

APPENDIX VII

JAN 12 1998 510(k) SUMMARY

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: October 3, 1997

NAME OF DEVICE: Applied Medical Laparoscopic Gastrostomy Kit

CLASSIFICATION NAME: Gastrointestinal Tube and Accessories

TRADE NAME: Not determined at this time

SUMMARY STATEMENT:

The Applied Medical Laparoscopic Gastrostomy Kit is indicated for use as a means of percutaneously inserting a feeding tube into the stomach through the abdominal wall. The Laparoscopic Gastrostomy Kit is disposable and designed to be used under laparoscopic visualization. The Kit includes (1 each):

- Electrosurgical Obturator / Stylet
- 26F Silicone Feeding Tube

All testing demonstrates that the Applied Medical Laparoscopic Gastrostomy Kit is equivalent to the predicate devices and introduces no new safety and effectiveness issues when used as indicated.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 12 1998

Howard V. Rowe
Director of Regulatory Affairs
Applied Medical Resources
26051 Merit Circle, #104
Laguna Hills, California 92653

Re: K973891
AMR Laparoscopic Gastrotomy Kit
Regulatory Class: II
21 CFR 876.5980/Procode: 78 KNT
21 CFR 878.4400/procode: 78 GCT
Dated: October 3, 1997
Received: October 14, 1997

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. However, you are responsible to determine that the medical devices you use as components in the kit have either been determined as substantially equivalent under the premarket notification process (Section 510(k) of the act), or were legally on the market prior to May 28, 1976, the enactment date of the Medical Device Amendments. *Please note:* If you purchase your device components in bulk (i.e., unfinished) and further process (e.g., sterilize) you must submit a new 510(k) before including these components in your kit. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, and 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, FDA will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, the Food and Drug Administration (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 the 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/dsmamain.html".

Sincerely yours,

Robert R Ratliff

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

K973891

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 Laparoscopic Gastrostomy Kit "Indication for Use" as required.

510(k) Number: Not Assigned

Device Name: Applied Medical Laparoscopic Gastrostomy Kit.

Indications for Use: The Laparoscopic Gastrostomy Kit is indicated for use as a means of percutaneously inserting a feeding tube into the stomach through the abdominal wall. The Laparoscopic Gastrostomy Kit is disposable and designed to be used under laparoscopic visualization.

Signature: _____ Title: Director, Regulatory Affairs Date: 10/9/97

(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)

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K973891

(Optional Format 1-2-96)