AUG 2 4 2006

510(k) SUMMARY

510(k) NUMBER: ~~PENDING~~ K062169

SUBMITTED BY:

Applied Medical Resources Corporation
22872 Avenida Empresa
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CONTACT PERSON:

Cheryl Blake
Vice President Regulatory Affairs

DATE OF PREPARATION: July 7, 2006

NAME OF DEVICE: Laparoscopic Disposable Monopolar Scissors

COMMON NAME: Laparoscopic Scissors

CLASSIFICATION NAME: Gynecologic laparoscope and accessories (Regulation Number 21CFR 884.1720)

Product Code HET

TRADE NAME: Applied Laparoscopic Disposable Monopolar Scissors

PREDICATE DEVICE: Applied Laparoscopic Monopolar Scissor (K040295)

INTENDED USE: The Applied Laparoscopic Monopolar Scissors is intended for use in general and gynecologic endoscopic procedures for mobilization and transection of tissue.

TECHNOLOGY CHARACTERISTICS: The Applied Laparoscopic Disposable Monopolar Scissor

SUMMARY STATEMENT:

The Applied Laparoscopic Disposable Monopolar Scissors is designed to for a variety of general and gynecologic endoscopic procedures for mobilization and transection of tissue. The Applied Laparoscopic Disposable Monopolar Scissors consists of a ratcheting handle attached to an insulated shaft with scissor blades.

The handle includes male cautery connector to be utilized for monopolar cautery when attached to standard monopolar cautery cables and their generators.

The scissor blade length is 17.4mm and the blade opening is 5.59mm and will be available in working lengths of 32cm, and 45cm. The device is to be supplied sterile in single unit pouches.

The device is in compliance with ISO 10993 for Biocompatibility. The Applied Laparoscopic Disposable Monopolar Scissors will be sterilized using a Cobalt 60 Gamma Radiation; AAMI/ISO Guideline for Radiation Sterilization will be utilized to provide a Sterility Assurance Level of 10^{-6}. The method of validation is AAMI FDS-1 TIR 27 2001 Radiation sterilization - Substantiation of 25 kGy as sterilization dose - Method VDMax. The validated does is 25 to 40 kGy.

The device is identical in materials and characteristics of the predicate device, with the exception of the insulated shaft. The predicate device utilized thermoplastic shrink tubing and the new device utilizes thermoplastic extruded tubing. The energy source, Monopolar Electrosurgical Energy, is the same energy type as used for the predicate device.

Design Analysis and comparisons, as well as bench testing, has been conducted to confirm the functional characteristics are substantially equivalent to the predicate device cited, and that the design output put meets the design input requirements.

The performance of the Applied Laparoscopic Disposable Monopolar Scissors is compared to the performance of the Applied Medical Laparoscopic Monopolar Scissors, which is cleared to market under premarket notification, K040295. Functional Performance Testing conducted includes the performance of the following tests:

a) Dielectric Withstand Testing per ANSI/AAMI HF-18: 2001
b) Cutting Functionality Test
c) Monopolar Functionality Test
d) Dimensional Comparison

Conclusion: Based upon the technical information, intended use, and performance information provided in the pre-market notification, the Applied Laparoscopic Disposable Monopolar Scissors and the Applied Laparoscopic Monopolar Scissor (K040295) has shown to be substantially equivalent, and the design control process confirm the that design outputs meets the design input requirements.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
9200 Corporate Blvd.
Rockville MD 20850

AUG 24 2006

Applied Medical Resources Corporation
% Mr. Jeffrey D. Rongero
Senior Project Engineer
Underwriters Laboratories, Inc.
1285 Walt Whitman Rd.
MELVILLE NY 11747

Re: K062169
Trade/Device Name: Applied Laparoscopic Disposable Monopolar Scissors
Regulation Number: 21 CFR 884.1720
Regulation Name: Gynecologic laparoscope and accessories
Regulatory Class: II
Product Code: HET
Dated: August 11, 2006
Received: August 14, 2006

Dear Mr. Rongero:

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 (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 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 Section 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:

21 CFR 876.xxx	(Gastroenterology/Renal/Urology	240-276-0115
21 CFR 884.xxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 894.xxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150
or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Nancy C Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K062169

Device Name: Applied Laparoscopic Disposable Monopolar Scissors

Indications for Use:

Indications for Use: The Applied Laparoscopic Monopolar Scissors is indicated for use in patients undergoing general, gynecologic and urologic endoscopic procedures for mobilization and transection of tissue.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D)

~~AND~~/OR

Over-The-Counter Use _____ (21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

David A Lehmann

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K062169

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