K103282

Applied Medical

510(k) SUMMARY

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NOV 16 2010

SUBMITTED BY: Applied Medical Resources Corporation
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CONTACT PERSON: Frans VandenBroek
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DATE OF PREPARATION: August 27, 2010

TRADE NAME: Laparoscopic Dissector

COMMON NAME: Tissue dissector

CLASSIFICATION NAME: Electrosurgical cutting and coagulating device and accessories, class II, CFR 878.4400, product code GEI

PREDICATE DEVICE: K984240, ENDOPATH Endoscopic Instruments

DEVICE DESCRIPTION: The Applied Medical Laparoscopic Dissector is a sterile, single use, disposable surgical instrument designed for minimally invasive surgical procedures. It fits through a trocar and is used to grasp, mobilize and dissect tissue. The dissector may be connected to a standard electrosurgical generator for performing monopolar cautery. The dissector is substantially equivalent to the predicate device in size, function, performance and indications for use.

INTENDED USE: The Applied Medical Laparoscopic Dissector is indicated for use during minimally invasive procedures for grasping, mobilizing, dissecting and cauterizing tissue.

SUMMARY OF TECHNOLOGICAL CHARACTERISTICS: The dissector shares a common design with Applied Medical's laparoscopic graspers and scissors. All are made of various polymers and stainless steel, and all feature a slender shaft with a handle at one end and articulated jaws (or scissor blades) at the tip. The shaft may be rotated 360° for optimum approach to tissue that is to be dissected. The handle is constructed in line with the shaft and is ergonomically shaped to fit the hand of the user. A toggle on the handle closes and opens the jaws. The curved articulated jaws are similar to the jaws of the predicate device.

As is the case with the predicate device, the jaws of Applied's dissector may be energized by a standard electrosurgical generator. An accessory cord connects the dissector to the generator which delivers monopolar energy to the jaws for cauterizing tissue.

The Applied laparoscopic dissectors will be manufactured with straight and angled shafts and in two different lengths. Packaging consists of a Tyvek/Mylar peel pouch and a carton. Sterilization is via gamma irradiation; sterility assurance level will be 10^{-6}.

DISCUSSION OF NONCLINICAL TESTS SUBMITTED: Applied Medical created a dedicated test method designed to confirm safety and efficacy of the dissector as well as substantial equivalence relative to the predicate device of K984240. These tests focused on:

- Dimensional comparison to predicate device
- Dielectric withstand (generator frequency) and establishment of voltage rating with the active electrode/insulated shaft
- Dielectric withstand (generator frequency) of device handle
- Dielectric withstand (mains frequency)
- Monopolar functionality
- Tissue holding, dissecting, piercing and opening
- Jaw clamping force test
- Thermal safety
- Mechanical abuse
- Environmental conditioning

CONCLUSIONS DRAWN FROM TESTING: Applied's performance and functional testing demonstrated that the Applied laparoscopic tissue dissector is substantially equivalent to the predicate device of K984240 and introduces no new safety and effectiveness issues.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Applied Medical Resources Corporation
% Underwriters Laboratories, Inc.
Mr. Casey Conry
1285 Walt Whitman Road
Melville, New York 11747

NOV 16 2010

Re: K103282
Trade/Device Name: Laparoscopic Dissector
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical cutting and coagulation device and accessories
Regulatory Class: Class II
Product Code: GEI
Dated: November 04, 2010
Received: November 05, 2010

Dear Mr. Conry:

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to 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); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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 (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

For

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
And Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

NOV 16 2010

INDICATIONS FOR USE

510(k) Number (if known): ~~Not yet assigned~~ K103282

Device Name: Laparoscopic Dissector

Indications for Use: The Laparoscopic Dissector is indicated for use during minimally invasive procedures for grasping, mobilizing, dissecting and cauterizing tissue.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K103282