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510(k) Summary

This 510(k) summary of safety and effectiveness information is being submitted in accordance with the requirements of 21 CFR 807.92.

510(K) Submitter:
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Date of Preparation: July 22, 2013

Trade Name: Epix® Electrosurgical Probes

Common Name: Electrosurgical Probes

Classification: Class II
Product Code: GEI Regulation: 21 CFR 878.4400

Predicate Device: Modulap™ Reusable Unipolar Electrosurgical Probes
510(k)#: K983623
Product Code: GCJ

Device Description: Electrosurgical probes are reusable suction and irrigation devices designed for electrosurgical cutting and coagulation of tissue during general laparoscopic procedures.

Intended Use: The Epix® electrosurgical probes are indicated for irrigation, evacuation of fluids, and electrosurgical cutting and coagulation during general laparoscopic procedures.

Summary of Technological Characteristics:

The Epix® Electrosurgical Probes are substantially equivalent in safety and effectiveness to the Modulap™ Reusable Unipolar Electrosurgical Probes (K983623).

The subject and predicate device are similar in tip-configuration, size, materials, technology, and performance. They are reusable, suction and irrigation devices designed for electrosurgical cutting and coagulation during general laparoscopic procedures. The subject and predicate electrosurgical probes are each designed to interface and function when connected to a suction irrigation tubing set and electrosurgical generator.

Discussion of Performance Testing:

The Epix Electrosurgical Probes are designed to the following safety and performance standards: IEC 60601-1 Medical electrical equipment – General requirements for safety, IEC 60601-1-2 Medical electrical equipment - Part 1-2: General requirements for safety - Collateral standard: Electromagnetic compatibility - Requirements and tests, IEC 60601-2-2 Medical electrical equipment – Part 2-2: Particular requirements for the basic safety and essential performance of high frequency surgical equipment and high frequency surgical accessories, and ISO 10993 Biological Evaluation of Medical Devices.

Applied Medical created a testing protocol to confirm substantial equivalency between the subject and predicate. The devices were tested side-by-side to evaluate substantial equivalence of performance in a laboratory setting. The bench top tests were designed to focus on the functional performance of the suction and irrigation features.

Conclusions Drawn from Testing:

Testing demonstrates that the subject Epix Electrosurgical Probes are substantially equivalent to the predicate Modulap Reusable Unipolar Electrosurgical Probes.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

Applied Medical Resources Corporation
Ms. Jessica Cho
Regulatory Affairs Specialist
22872 Avenida Empresa
Rancho Santa Margarita, California 92688

January 24, 2014

Re: K132300
Trade/Device Name: Epix® Electrosurgical Probes
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical cutting and coagulation device and accessories
Regulatory Class: Class II
Product Code: GEI
Dated: January 14, 2014
Received: January 16, 2014

Dear Ms. Cho:

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 contact 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. 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,

Joshua C. Nipper -S

Binita S. Ashar, M.D., M.B.A., F.A.C.S.
For Acting Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE

510(K) Number: K132300

Device Name: Epix® Electrosurgical Probes

Indications for Use: The Epix® Electrosurgical Probes are indicated for irrigation, evacuation of fluids, and electrosurgical cutting and coagulation during general laparoscopic procedures.

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)

Long H. Chen -A

Digitally signed by Long H. Chen -A
DN: c=US, o=U.S. Government, ou=HHS, ou=FDA, ou=People, cn=Long H. Chen -A, 0.9.2342.19200300.100.1.1=1300369056
Date: 2014.01.23 14:24:42 -05'00'

for BSA

(Division Sign-Off)
Division of Surgical Devices
510(k) Number: K132300