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

August 7, 2017

Applied Medical Resources Corporation
Aditi Iyengar
Regulatory Affairs Analyst
22872 Avenida Empresa
Rancho Santa Margarita, California 92688

Re: K171684
Trade/Device Name: Epix Electrosurgical Probe with Smoke Evacuation
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical Cutting and Coagulation Device and Accessories
Regulatory Class: Class II
Product Code: GEI
Dated: June 6, 2017
Received: June 7, 2017

Dear Aditi Iyengar:

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 Industry and Consumer Education 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" (21 CFR 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 Industry and Consumer Education 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,

Jennifer R. Stevenson -S3

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

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)* K171684

Device Name
Epix® Electrosurgical Probe with Smoke Evacuation

Indications for Use *(Describe)*
The Epix Electrosurgical Probe with Smoke Evacuation is intended to deliver energy from an independent monopolar electrosurgical generator to cut and coagulate tissue during laparoscopic surgical procedures where the device is introduced into the body through a cannula. The device may be used for the evacuation of smoke created by electrosurgery at the surgical site.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) Summary

510(K) Submitter:

Applied Medical Resources Corporation
22872 Avenida Empresa
Rancho Santa Margarita, CA, 92688
(949) 713-8000

Contact Person:

Aditi Iyengar
Regulatory Affairs Analyst
Applied Medical Resources
aiyengar@appliedmedical.com
Tel: (949) 713-8007
Fax: (949) 713-8205

Date of Preparation: June 6, 2017

Trade Name: Epix® Electrosurgical Probes with Smoke Evacuation

Common Name: Smoke Evacuation Electrosurgery Probes

Classification: Electrosurgical cutting and coagulation device and accessories.
Regulation: 21 CFR 878.4400
Device Class: Class II
Product Code: GEI

Predicate Device: Epix® Electrosurgical Probes
510(k)#: K132300
Product Code: GEI

Device Description: The Epix Electrosurgical Probe with Smoke Evacuation is a sterile, single-use monopolar instrument equipped with a smoke evacuation feature. The proposed device uses RF energy provided by a generator to electrosurgically cut and/or coagulate tissue during general laparoscopic procedures. The electrosurgical probes are available in three different tip geometries with probe lengths ranging between 20cm - 45cm. All models are constructed of the same materials and by similar manufacturing assembly processes. The following configurations will be available:

Probe Length	Probe Configuration	Model Number
20 cm	Spatula Tip	CW011
	L-Hook Tip	CW012
	Needle Tip	CW013
27 cm	Spatula Tip	CW021
	L-Hook Tip	CW022
	Needle Tip	CW023

Probe Length	Probe Configuration	Model Number
35 cm	Spatula Tip	CW031
	L-Hook Tip	CW032
	Needle Tip	CW033
42cm	Spatula Tip	CW001
	L-Hook Tip	CW002
	Needle Tip	CW003
45cm	Spatula Tip	CW041
	L-Hook Tip	CW042
	Needle Tip	CW043

Intended Use: The Epix Electrosurgical Probe with Smoke Evacuation is intended to deliver energy from an independent monopolar electrosurgical generator to cut and coagulate tissue during laparoscopic surgical procedures where the device is introduced into the body through a cannula. The device may be used for the evacuation of smoke created by electrosurgery at the surgical site.

Comparison of Technological Characteristics with the Predicate Device

The subject and predicate electrosurgical probes are similar in technological characteristics, materials, performance, and method of operation. They are designed to deliver RF energy via connection to an independent monopolar generator to electrosurgically cut and coagulate tissue during general laparoscopic procedures. The subject and predicate probes are both compatible with standard monopolar electrosurgical generators such as the Medtronic® ForceTriad® generator (K110268), ConMed® System 5000™ generator (K020186), or Karl Storz ® AUTOCON ® II 400 SCB generator (K062464), using a standard 4mm monopolar female connector. Additionally, both subject and predicate probes are also equipped with a suction feature to aid in visualization of the surgical site.

The following technological differences exist between the subject and predicate electrosurgical probes:

- The suction feature on the subject device is intended to evacuate smoke while the suction feature on the predicate device is intended to aspirate fluid.
- The subject product line is available in an additional tip configuration, needle tip, and the shaft length of the subject probe is available in the range of 20cm – 45cm where the predicate probe was cleared with a 33cm length.

Table 1 below provides a more detailed comparison of the subject and predicate electrosurgical probes.

Table 1: Comparison of Characteristics

	Predicate **Epix Electrosurgical Probes**	**Subject** **Epix Electrosurgical Probes with Smoke Evacuation**
Trade Name	Epix Electrosurgical Probes	Epix Electrosurgical Probe with Smoke Evacuation

	Predicate **Epix Electrosurgical Probes**	**Subject** **Epix Electrosurgical Probes with Smoke Evacuation**
Probe Tip Configurations	• Spatula Tip • L-Hook Tip • J-Hook Tip	• Spatula Tip • L-Hook Tip • Needle Tip
510(k) Holder	Applied Medical Resources Corporation	Same as predicate
510(k) Number	K132300	K171684
Regulation	21 CFR §878.4400	Same as predicate
FDA Product Code	GEI	Same as predicate
Device Classification	FDA Class II	Same as predicate
Type of Use	Prescription Use Only	Same as predicate
Energy Type	Monopolar	Same as predicate
Energy source	Electrosurgical generator provided by user	Same as predicate
Cable compatibility	Standard 4mm monopolar cables	Same as predicate
Materials	Stainless Steel, polymers	Same as predicate
Shaft Properties	• 33cm working length • 360 ° rotation • Straight	• 20cm - 45cm working lengths • 360 ° rotation • Angled at distal end
Single Use	No	Yes
Standards	Conforms to: • ISO 10993-series • IEC 60601-1 • IEC 60601-1-2 • IEC 60601-2-2 • IEC 60601-2-18 • AAMI TIR 17 • ANSI AAMI ST79	Conforms to: • ISO 10993-series • IEC 60601-1 • IEC 60601-1-2 • IEC 60601-2-2 • IEC 60601-2-18 • ISO 11137-2 • AAMI TIR 33

Performance Data

The performance data in Table 2 is provided in support of the substantial equivalence determination.

Table 2: Substantial Equivalence Tests

Test	Result
Electrosurgical Performance	Substantially Equivalent
Smoke Evacuation Performance	Substantially Equivalent

The performance data in Table 3 is provided to demonstrate safety and efficacy of the subject devices.

Table 3: Performance Tests

Test	Result
Biocompatibility	Met Acceptance Criteria
Mechanical Testing	Met Acceptance Criteria
Electrical Safety Testing	Met Acceptance Criteria
Electromagnetic Compatibility (EMC) Testing	Met Acceptance Criteria

No animal or clinical studies were required to demonstrate the safety and efficacy of the subject device in support of this application for premarket clearance. The non-clinical performance data detailed in this submission supports the substantial equivalence of the subject device.

Conclusion

Based on the intended use, technological characteristics, and performance testing results, the subject Epix Electrosurgical Probes with Smoke Evacuation are substantially equivalent to the predicate Epix Electrosurgical Probes and do not raise any new issues of safety and efficacy.