K123061

510(k) Summary

5.1 **Type of Submission:** Traditional

5.2 **Preparation Date:** Sep 28, 2012

AUG 1 3 2013

5.3 **Revised Date:** August 09 , 2013

5.4 **Submitter:** BioEconeer Inc.

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Contact: Tony ChaoFu Chang

Establishment Registration Number: N/A

5.5 **Identification of the Device:**

Proprietary/Trade name:	ACE Monopolar Attachment
Common Name:	Electrosurgical, Cutting & Coagulation & Accessories
Classification Name:	Electrosurgical, Cutting & Coagulation & Accessories
Device Classification:	II
Regulation Number:	878.4400
Panel:	General & Plastic Surgery
Product Code:	GEI

5.6 **Identification of the Predicate Device:**

Predicate Device Name:	GEIGER DISPOSABLE ELECTROSURGICAL ELECTRODE
Manufacturer:	GEIGER MEDICAL TECHNOLOGIES, INC.

510(k) Number or Clearance Information: K994075

5.7 Intended Use and Indications for Use of the subject device.

The ACE Monopolar Attachment is intended to be used with the compatible ERBE Monopolar Disposable Electrosurgical Pencil (model: No.20190-109) for coagulation and cutting of soft tissue when used in conjunction with compatible ERBE Electrosurgical Generator (ESU) Systems.

5.8 Device Description

The ACE Monopolar Attachment is used with compatible ERBE Electrosurgical Generator (ESU) Systems which deliver High Frequency (HF) energy through the electrode tip of the ACE Monopolar Attachment for coagulation and cutting of soft tissue. The ACE Monopolar Attachment is an electrode tip, made of stainless steel, and compatible with marketed plastic insulation handle. The compatible ERBE Electrosurgical Unit (ESU) to be used must have a Monopolar 3-pin bovie receptacle. The Monopolar Attachment is provided single-use.

5.9 Non-clinical Testing

A series of preclinical physical, mechanical and biocompatibility tests were performed to assess the safety and effectiveness of the ACE Monopolar Attachment. The safety tests were conducted *in vitro* and *in vivo* in accordance with **ISO 10993-1:2009, Biological evaluation of medical devices -- Part 1: Evaluation and testing within a risk management process, ISO 10993-5: 2003, Biological evaluation of medical devices -- Part 5: Tests for In Vitro cytotoxicity, ISO 10993-10:2002/Amd. 1:2006(E), Biological evaluation of medical devices - Part 10: Tests for irritation and delayed-type hypersensitivity AMENDMENT 1, IEC 60601-1, Medical Electrical Equipment - Part 1: General Requirements for Safety, 1988; Amendment 1, 1991-11, Amendment 2, 1995, IEC 60601-1-2:2007, Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests (Edition 3), IEC 60601-2-2:2009, Medical electrical equipment - Part 2-2: Particular requirements for the basic safety and essential performance of high frequency surgery equipment and high frequency surgical accessories, ISO 11137-2:2006, Sterilization of health care products - Radiation - Part 2: Establishing the sterilization dose, and ASTM D7334-08 Standard Practice for Surface Wettability of Coatings, Substrates and Pigments by Advancing Contact Angle Measurement.**

The Performance Tests were conducted on the subject device and the predicate device for the *ex vivo* test and mechanical test items listed below:

Ex vivo test: Arcing Test, Charring Test, Thermal Spread Test

Mechanical test: Dropping Test, Pulling Test

All the test results demonstrate the safety and performance of ACE Monopolar Attachment meets the requirements of its pre-defined acceptance criteria and intended uses.

5.10 Safety and Effectiveness

The results of the non-clinical testing demonstrate that the ACE Monopolar Attachment is substantially equivalent to the predicate devices.

5.11 Substantial Equivalence Determination

The ACE Monopolar Attachment submitted in this 510(k) file is substantially equivalent in intended use, design, technology/principles of operation, materials and performance to the cleared GEIGER Disposable Electrosurgical Electrode which is the subject of K994075. Differences between the devices cited in this section do not raise any new issues of safety or effectiveness.

Item	**Predicate Device** (GEIGER Disposable Electrosurgical Electrode)	**Proposed Device** (ACE Monopolar Attachment)
Similarity		
Classification	Class II	Class II
Code or Federal Regulations	878.4400	878.4400
Prescription Medical Devices	YES	YES
Intended Use	The Geiger Disposable Electrosurgical Electrode is intended to be utilized for basic non-sterile electrosurgical procedures. Examples of non-sterile procedures include the removal of	The ACE Monopolar Attachment is intended to be used with the compatible ERBE Monopolar Disposable Electrosurgical Pencil (model: No.20190-109) for coagulation

		moles, warts and skin tags. The electrodes are a standard 3/32" in diameter and will fit the majority of electrosurgical generators and handpieces in the marketplace.	and cutting of soft tissue when used in conjunction with compatible ERBE Electrosurgical Generator (ESU) Systems.
Material of electrode tip		Stainless Steel	Stainless Steel
Dimension		Shaft: 3/32"	Shaft: ϕ 2.35mm
Safety Standards		ISO 10993-1 ISO 10993-5 ISO 10993-10 IEC 60601-1 IEC 60601-1-2 IEC 60601-2-2 ISO 11137-2 ASTM D7334-08	ISO 10993-1 ISO 10993-5 ISO 10993-10 IEC 60601-1 IEC 60601-1-2 IEC 60601-2-2 ISO 11137-2 ASTM D7334-08
Performance Standards		Not applicable	Not applicable
Comparative Performance Test Items	*Ex vivo*	Arcing Test Charring Test Thermal Spread Test	
	Mechanical	Dropping Test Pulling Test	
Differences			
Material of insulation		polystyrene	Nylon
Sterilization		non-sterile	Gamma irradiation (Single Use)

The differences between the subject device and predicate device are on the material of insulation and sterilization. The subject device has tested on safety and performance tests and the test results were complied with the test requests. Therefore, the differences of subject device and predicate device didn't raise any problems of safety or effectiveness. The ACE Monopolar Attachment is substantially equivalent to the predicate device in design, operation, intended use, method of preparation, and performance claims.

5.12 Conclusion

After analyzing bench tests, electrical safety testing data, it can be concluded that ACE Monopolar Attachment is substantially equivalent to the predicate device.

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

BioEconeer Incorporated
% Michael Lee
President
AcmeBiotechs Company, Ltd.
No.45, Minsheng Road, Danshui District
New Taipei City, Taiwan 251

August 13, 2013

Re: K123061
Trade/Device Name: ACE Monopolar Attachment
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical cutting and coagulation device and accessories
Regulatory Class: Class II
Product Code: GEI
Dated: July 19, 2013
Received: July 26, 2013

Dear Mr. Lee:

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,

Peter D. Rumm -S

Mark N. Melkerson
Acting Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K123061

Device Name: ACE Monopolar Attachment

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Prescription Use ___X___ AND/OR Over-The-Counter Use_____

(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

DSD—DIVISION SIGN-OFF

Division of Surgical Devices

510(k) Number: K123061

Joshua C. Nipper -S