DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

August 22, 2014

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

Re: K141288
Trade/Device Name: Voyant® Electrosurgical Generator and Voyant® 5mm Sealer-Divider System
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical cutting and coagulation device and accessories
Regulatory Class: Class II
Product Code: GEI
Dated: July 22, 2014
Received: July 23, 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 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" (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 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 yours,

David Krause -S

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

INDICATIONS FOR USE

Device Name: Voyant® Electrosurgical Generator and Voyant® 5mm Sealer-Divider System

Indications for Use:

The Voyant electrosurgical generator is indicated for use with Voyant devices in open and laparoscopic surgical procedures where the electrosurgical ligation of vessels or tissue bundles is desired.

The Voyant 5mm Sealer-Divider device is a bipolar, electrosurgical device indicated for use with the Voyant electrosurgical generator in laparoscopic procedures where the ligation and division of vessels and tissue bundles is desired.

The device can seal and divide vessels up to and including 7mm in diameter and tissue bundles that can be captured in the jaws of the device.

The device has not been shown to be effective for tubal sterilization or tubal coagulation for sterilization procedures, and should not be used for these 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)

510(k) Summary

510(k) Submitter: Applied Medical Resources Corp.
22872 Avenida Empresa
Rancho Santa Margarita, CA 92688
(949) 713 – 8000

Contact Person: Jessica Cho
Regulatory Affairs Specialist
Applied Medical Resources
Tel: (949) 713 – 7958
Fax: (949) 713 – 8205
Email: jcho@appliedmedical.com

Preparation Date: May 14, 2014

Trade Name: Voyant® Electrosurgical Generator and Voyant® 5mm Laparoscopic Tissue Sealer-Divider Device

Common Name: Electrosurgical Generator
Bipolar Electrosurgical Sealer-Divider

Classification: Electrosurgical Cutting and Coagulation Device and Accessories, General and Plastic Surgery Devices, 21 CFR 878.4400, Product Code GEI

Predicate Devices: Trade Name: LigaSure™ 5mm Blunt Tip Laparoscopic Sealer-Divider
510(k) #: K092879
Product Code: GEI

Trade Name: ForceTriad™ Electrosurgical Generator
510(k) #: K070162
Product Code: GEI

Device Description: The Applied Medical Voyant Electrosurgical Generator (ESG) is a tabletop radiofrequency (RF) power supply designed for use in electrosurgery. It operates outside the sterile field and is equipped with receptacles for Applied Medical bipolar devices. The ESG enclosure is constructed of various metals and polymers and houses all electrical hardware and software components. The front panel features an LCD and backlit buttons for the navigation, adjustment, and selection of ESG and device settings.

The Applied Medical Voyant 5mm Laparoscopic Tissue Sealer-Divider instrument is designed for use with the Voyant ESG. This device is an advanced bipolar instrument that uses RF energy, provided by the generator, to seal vessels up to and including 7mm in diameter. The device may also be used to seal tissue bundles that can be captured in the device jaws. The device features a mechanical, user-actuated blade for the division of sealed tissue.

Intended Use:

The Voyant electrosurgical generator is indicated for use with Voyant devices in open and laparoscopic surgical procedures where the electrosurgical ligation of vessels or tissue bundles is desired.

The Voyant 5mm Sealer-Divider device is a bipolar, electrosurgical device indicated for use with the Voyant electrosurgical generator in laparoscopic procedures where the ligation and division of vessels and tissue bundles is desired.

The device can seal and divide vessels up to and including 7mm in diameter and tissue bundles that can be captured in the jaws of the device.

The device has not been shown to be effective for tubal sterilization or tubal coagulation for sterilization procedures, and should not be used for these procedures.

Summary of Technological Characteristics between Subject and Predicate:

The subject and predicate generators are technologically similar in that both are electrically isolated, microprocessor controlled, tabletop RF power supplies designed for use in electrosurgery. The generators are designed to provide RF energy to connected bipolar instruments with fuse energy modes. Both generators are equipped with a graphical user interface that allows the user to adjust the energy output settings. The generators are dissimilar in that the predicate generator supports electrosurgical cutting and coagulation as well as monopolar and standard bipolar instruments, where the subject device does not.

The subject and predicate instruments are technologically similar in size, configuration, and operation. They are designed to deliver RF energy to vessels up to 7mm and tissue captured between the jaws of the device for tissue fusion. Both instruments feature pistol-grip style handles with a trigger for jaw closure and button on the back of the handle for energy activation. The instruments are equipped with a mechanical, user-actuated blade for the division of sealed tissue. The instruments are dissimilar in that the subject jaws are capable of uninterrupted 360° rotation where the predicate jaws have 159° of rotation.

Discussion of Performance Testing Submitted:

Testing was performed on the subject Voyant® system to demonstrate electrical, mechanical and functional capabilities in accordance with IEC 60601-1, IEC 60601-1-2 and IEC 60601-2-2. The subject system was also tested side-by-side against the predicate system to evaluate substantial equivalence with respect to performance in a laboratory setting as well as an animal model. Side-by-side testing focused on the seal quality evaluation and the local tissue effects of the applied RF energy in and surrounding the seal.

Non-clinical: Basic mechanical and functional capabilities were tested for the subject electrosurgical generator and subject sealer-divider. The following is a summary of components and testing performed:

- Electrosurgical Generator
    - Energy output

    - Static and Dynamic Load testing
- Sealer-Divider Device
    - Mechanical strength testing per IEC 60601-1
    - Durability testing
    - Destructive testing per IEC 60601-2-2
- Integrated System
    - Electrical safety testing per IEC 60601-1
    - Safety systems testing

Preclinical: Preclinical bench (*ex vivo* porcine vessels/tissue) and animal (*in vivo* canine model) studies were performed to evaluate system safety and efficacy and to demonstrate that the subject device performance is substantially equivalent to the predicate device; namely:

- Preclinical (*ex vivo*)
    - Seal evaluation
    - Thermal damage
    - Burst pressures
- Acute animal study (*in vivo*)
    - Seal evaluation
    - Thermal damage

In addition, a chronic study (*in vivo* canine model) was conducted using the subject system to evaluate seal quality and chronic hemostasis.

Clinical: This premarket notification does not rely on human clinical trial data to demonstrate substantial equivalence

Conclusions Drawn from Testing:

The Applied Medical Voyant system is substantially equivalent in performance to the predicate system with respect to vessel sealing performance and local tissue effects.