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

June 1, 2016

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

Re: K153288
Trade/Device Name: Voyant Open Fusion Device
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical cutting and coagulation device and accessories
Regulatory Class: Class II
Product Code: GEI
Dated: April 22, 2016
Received: April 25, 2016

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" (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 yours,

Jennifer R. Stevenson -A

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)*
K153288

Device Name

Voyant Open Fusion Device

Indications for Use *(Describe)*

The Voyant Open Fusion device is a bipolar, electrosurgical device indicated for use with the Voyant electrosurgical generator in open procedures where the ligation and division of vessels and tissue bundles is desired.

The device can seal and divide vessels up to and including 5mm 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.

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.

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510(k) Summary

510(k) Submitter: Applied Medical Resources Corp.
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Preparation Date: November 12, 2015

Trade Name: Voyant® Open Fusion Device

Common Name: 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 Device: Voyant® Open Fusion Device (K143517)

Device Description: The Applied Medical Voyant Open Fusion instrument is designed for use with the Voyant ESG (cleared in K141288). This device is an advanced bipolar instrument that uses RF energy, provided by the generator, to seal vessels up to and including 5mm 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 Open Fusion device is a bipolar, electrosurgical device indicated for use with the Voyant electrosurgical generator in open procedures where the ligation and division of vessels and tissue bundles is desired.

The device can seal and divide vessels up to and including 5mm 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 device design is the same as the predicate, with the exception of an updated sealing surface design and software updates. The subject design has the same fundamental technological features and intended use as the predicate.

The subject and predicate instruments are technologically similar in size, configuration, and operation. They are designed to deliver RF energy to vessels 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.

Discussion of Performance Testing:

A summary of performance testing was included to characterize the subject Open Fusion device. Testing evaluated the subject device's electrical, mechanical and functional capabilities. The subject device was also compared against the predicate to evaluate substantial equivalence with respect to performance in a laboratory setting as well as an animal model. Testing used for subject-predicate comparison 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 Open Fusion. The following is a summary of testing discussed:

- Simulated repeated use testing
- Safety systems testing

Preclinical: Preclinical bench (*ex vivo* porcine vessels/tissue) and animal (*in vivo* porcine model) studies were summarized 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
    - Burst pressures
- Acute animal study (*in vivo*)
    - Seal evaluation
    - Thermal damage

In addition, chronic studies (*in vivo* porcine and ovine models) using the subject device to evaluate seal quality and chronic hemostasis were discussed.

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

Conclusions Drawn from Testing:

The Applied Medical Voyant Open Fusion is substantially equivalent in performance to the predicate device with respect to intended use (i.e., vessel sealing performance and local tissue effects).