DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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Silver Spring, MD 20993-0002

July 6, 2016

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

Re: K153017
Trade/Device Name: Voyant Fine Fusion
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical cutting and coagulation device and accessories
Regulatory Class: Class II
Product Code: GEI
Dated: May 31, 2016
Received: June 1, 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 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" (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 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,

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)*
K153017

Device Name

Voyant Fine Fusion

Indications for Use *(Describe)*
The Voyant Fine Fusion device is a bipolar, electrosurgical device indicated for use with the Voyant electrosurgical generator in open procedures, including head and neck procedures, where 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.

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: October 13, 2015

Trade Name: Voyant® Fine Fusion

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 Devices: Trade Name: LigaSure Curved, Small Jaw, Open Sealer/Divider
510(k) #: K113572, Product Code: GEI

Trade Name: Voyant Fine Fusion
510(k) #: K143536, Product Code: GEI

Device Description: The Applied Medical Voyant Fine 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 7mm in diameter and in head and neck procedures. 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 Fine Fusion device is a bipolar, electrosurgical device indicated for use with the Voyant electrosurgical generator in open procedures, including head and neck procedures, where 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.

***Substantial equivalence discussion between Subject and Predicate*:**

The subject device is similar in construction to the previously cleared Fine Fusion device (K143536). The difference between the two devices is the indications for use and minor design changes that do not impact the overall functionality of the device. The minor design changes include:

- Material changes
  - Cosmetic color changes that are not related to function
  - Addition of a mechanical lubricant

- The previously cleared Fine Fusion had two tactile clicks during activation. Squeezing the ring handles to the second click resulted in energy output. The device was updated to have only a single click to activate RF output.

The main difference between the subject device and previously cleared Fine Fusion is the indications for use.

The subject and LigaSure predicate instruments are technologically similar in size, configuration, and operation. They are designed to deliver RF energy to vessels up to 7mm and tissue bundles captured between the jaws of the device for tissue fusion. Both instruments are used in head and neck procedures and feature scissor-grip style handles with ring handles for opening and closing the jaws and a button between the handles for energy activation. The instruments are equipped with a mechanical, user-actuated blade for the division of sealed tissue.

***Discussion of Performance Testing*:**

Biocompatibility

The subject device is an *external communicating device* in contact with *tissue/bone/dentin* for a *limited* duration (<24 hours). The following tests were conducted on the Fine Fusion:

- Cytotoxicity (per ISO 10993-5)
- Intracutaneous Reactivity (per ISO 10993-10)
- Sensitization (per ISO 10993-10, ASTM F2148)

The device passed all biocompatibility testing according to the acceptance criteria contained in the respective standards.

Sterilization

Validation of the sterilization process for this device was performed according the recognized consensus standards ISO 11137-2 and AAMI TIR 33.

The subject device is a single use sterilized device. The packaging, sterilization method, and shelf life of the subject device are identical to that of the previously cleared Voyant Fine Fusion device (K143536).

EMC (Electromagnetic Compatibility)

There have been no changes to the subject device that impact its electromagnetic compatibility (EMC) as presented in K143536. The device was designed and previously tested according to the applicable sections of IEC 60601-1-2 and IEC 60601-2-2.

Electrical Safety

The Voyant Fine Fusion Device is an electrosurgical instrument intended to contact the patient and has been designed in consideration of electrical safety. An electrical safety evaluation of the Fine Fusion was been conducted according to the applicable sections of IEC 60601-1 and IEC 60601-2-2 and presented in K143536.

Relevant tests from these standards were repeated to confirm the safety of the updated button design.

Substantial equivalence testing

The subject device was tested side-by-side against the LigaSure predicate to evaluate substantial equivalence with respect to performance in a laboratory setting as well as an animal model. Side-by-side testing focused on thermal performance, the seal quality evaluation and the local tissue effects of the applied RF energy in and surrounding the seal for the expanded indications including vessels up to 7mm in diameter and head and neck procedures.

Preclinical: Preclinical bench (*ex vivo* porcine vessels/tissue) and animal (*in vivo* ovine 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 for the expanded indications including vessels up to 7mm in diameter and head and neck procedures; namely:

- Bench (*ex vivo*)
  - Seal evaluation
  - Burst pressures of arteries and veins
- Acute animal studies (*in vivo*)
  - Seal evaluation
  - Thermal damage and thermal spread
    - Minimum, maximum, median, mode

In addition, chronic studies (*in vivo* ovine and canine model) were conducted using the subject device to evaluate long term seal quality and resulted in chronic hemostasis and no signs of hematomas.

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

Substantial Equivalence:

A comparison of intended use, technological characteristics, physical configuration, and performance of the subject Applied Medical Voyant Fine Fusion device to both predicate devices has shown that the subject device is substantially equivalent. This supports the expanded indications from the previously cleared Voyant Fine Fusion device (K143536) to include head and neck procedures and vessels up to 7mm in diameter.