



Food and Drug Administration
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April 16, 2015

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

Re: K143536

Trade/Device Name: Voyant Fine 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: March 13, 2015
Received: March 17, 2015

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,

Jennifer R. Stevenson -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

510(k) Number (if known)

K143536

Device Name

Voyant Fine Fusion

Indications for Use (Describe)

The Voyant Fine Fusion 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 3mm 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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(949) 713 – 8000
- Contact Person:* Jessica Cho
Manager, Regulatory Affairs
Applied Medical Resources
Tel: (949) 713 – 7958
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Email: jcho@appliedmedical.com
- Preparation Date:* April 15, 2014
- 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 Device:* Trade Name: LigaSure Curved, Small Jaw, Open Sealer/Divider
510(k) #: K102470, 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 3mm 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 Fine Fusion 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 3mm 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 instruments are technologically similar in size, configuration, and operation. They are designed to deliver RF energy to vessels up to 3mm and tissue captured between the jaws of the device for tissue fusion. Both instruments 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 Submitted:

Testing was performed on the subject Voyant® device to demonstrate electrical, mechanical and functional capabilities in accordance with IEC 60601-1, IEC 60601-1-2 and IEC 60601-2-2. The subject device was also tested side-by-side against the 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 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 Fine Fusion. The following is a summary of components and testing performed:

- 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, IEC 60601-2-2
 - Electromagnetic compatibility testing per IEC 60601-1-2
 - 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:

- Bench (*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 device to evaluate seal quality and chronic hemostasis and no signs of hematomas.

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

Biocompatibility: The patient contact materials of the subject Fine Fusion device were verified for biocompatibility in accordance with ISO 10993, FDA Blue Book Memorandum #G95-1, and the 2013 FDA Draft Guidance document *Use of International Standard ISO 10993, "Biological Evaluation of Medical Devices Part 1: Evaluation and Testing"*. The device passed all biocompatibility testing according to the acceptance criteria contained in the respective standards.

Sterilization: Validation of the sterilization process for the Fine Fusion was performed in accordance with ISO 11137-2 and AAMI TIR 33. The Fine Fusion Device is validated to an SAL of 10^{-6} .

Shelf Life: Testing was conducted on aged and conditioned units to ensure that the sterile barrier is maintained throughout the device's shelf life. Ship testing, including simulated transit and storage conditions such as drop, vibration, and compression, was performed to ensure the Fine Fusion device packaging will protect the units from damage during transit and handling. Environmental conditioning was performed per ISTA P2A and included exposure to temperature extremes and humidity. Shelf life testing met all the acceptance criteria.

Conclusions Drawn from Testing:

The Applied Medical Voyant Fine Fusion is substantially equivalent in performance to the predicate device for vessels up to and including 3 mm (i.e., vessel sealing performance and local tissue effects).