February 13, 2018

Applied Medical Resources Corporation
Andrew Nguyen
Regulatory Affairs Analyst
22872 Avenida Empresa
Rancho Santa Margarita, California 92688

Re: K172624
Trade/Device Name: Voyant 5mm 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: September 28, 2017
Received: September 29, 2017

Dear Andrew Nguyen:

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.

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.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Jennifer R. Stevenson -S3

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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K172624

Device Name
Voyant 5mm Fusion Device

Indications for Use *(Describe)*
The Voyant 5mm Fusion 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.

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 Corporation
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Preparation Date: August 31, 2017

Trade Name: Voyant® 5mm Fusion Device

Common Name: Bipolar Electrosurgical Sealer-Divider

Classification: General and Plastic Surgery Devices – Electrosurgical Cutting and Coagulation Device and Accessories
Regulation: 21 CFR 878.4400
Device Class: Class II
Product Code: GEI

Predicate Device: Voyant® 5mm Laparoscopic Tissue Sealer-Divider Device
510(k)#: K141288
Product Code: GEI

Device Description: The Voyant 5mm Fusion device is an advanced bipolar instrument that uses RF energy, provided by the Voyant Electrosurgical Generator (K141288), 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 5mm Fusion 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 Devices:

The subject device design is the same as the predicate, with the exception of the shaft length. The subject design has the same fundamental technological features and intended use as the predicate.

The subject and predicate instruments are technologically identical in 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:

The 2016 FDA Guidance, *Premarket Notification (510(k)) Submissions for Bipolar Electrosurgical Vessel Sealers for General Surgery,* was considered in evaluating the subject device's electrical, mechanical and functional capabilities. The tests addressed below were utilized to demonstrate safety and efficacy of the subject device and substantial equivalence to the predicate device.

EMC, Electrical Safety, and Mechanical Testing
The Voyant 5mm Fusion Device complies with IEC 60601-1:2005 for mechanical testing, IEC 60601-1:2005 and IEC 60601-2-2:2009 for electrical safety testing, and IEC 60601-1-2:2007 for electromagnetic compatibility testing.

Bench
Burst pressure testing was conducted on the subject and predicate Voyant 5mm Fusion Devices. Vessels representative of the devices' indications were sealed and the burst pressure for each vessel was recorded. The results of the study demonstrated that the subject device met the predetermined acceptance criteria.

Thermal spread testing was performed to evaluate the thermal spread damage produced by the subject and predicate Voyant 5mm Fusion Devices. Vessels representative of the devices' indications were sealed and measurements of the fused areas were taken. Analysis of the measurements demonstrated that the subject device met the predetermined acceptance criteria.

Clinical
No animal or clinical studies were required to demonstrate the safety and efficacy of the subject device in support of this application for premarket clearance. The performance data detailed in this submission supports the substantial equivalence of the subject device.

Software Verification
Unit, integration, and system level verification were conducted to evaluate the implementation and performance of the device software script.

Conclusion:

The subject Voyant 5mm Fusion Device is substantially equivalent in performance to the predicate Voyant 5mm Fusion Device with respect to intended use (i.e. vessel sealing performance and local tissue effects) and does not raise any new issues of safety and efficacy.