June 5, 2020

Applied Medical Resources Corp.
Sherif Nakhla
Regulatory Affairs Specialist
22872 Avenida Empresa
Rancho Santa Margarita, California 92688

Re: K201212
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: May 5, 2020
Received: May 5, 2020

Dear Sherif Nakhla:

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; 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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). 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 (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Long Chen, Ph.D.
Assistant Director
DHT4A: Division of General Surgery Devices
OHT4: Office of Surgical
and Infection Control Devices
Office of Product Evaluation and Quality
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)*
K201212

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 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.

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)*
K201212

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 open and 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)

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This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(k) Summary

510(k) Submitter: Applied Medical Resources Corporation
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Preparation Date: 05/05/2020

Trade Name: Voyant® Open Fusion Device & 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

Primary Predicate Device: Voyant® Open Fusion Device
510(k)#: K180699
Product Code: GEI

Voyant® 5mm Fusion Device
510(k)#: K193292
Produce Code: GEI

Device Descriptions: The Voyant Open Fusion and Voyant 5mm Fusion devices are advanced bipolar instruments that use RF energy, provided by the Voyant Electrosurgical Generator (K182244), to seal vessels up to and including 7mm in diameter. The devices may also be used to seal tissue bundles that can be captured in the devices' jaws. Each device features a mechanical, user-actuated blade for the division of sealed tissue.

Intended Use: The Voyant Open Fusion and Voyant 5mm Fusion devices are bipolar, electrosurgical devices intended for use with the Voyant Electrosurgical Generator to seal and divide vessels and tissues bundles.

Indications For Use:

Voyant Open Fusion Device:

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 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.

Voyant 5mm Fusion Device:

The Voyant 5mm Fusion device is a bipolar, electrosurgical device indicated for use with the Voyant electrosurgical generator in open and 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 Differences between Subject and Predicate Devices:

The subject and predicate devices are single-use, electrosurgical devices designed to achieve tissue fusion (via RF energy) on vessels and tissue captured between the device jaws. The devices feature a pistol-grip style handle with a trigger for jaw closure and a button for energy activation. The devices are equipped with a mechanical, user-actuated blade for the division of sealed tissue.

Each subject device design is the same as its respective predicate, with the exceptions of the change in software for both devices, the design of the Voyant Open Fusion device plug was updated, and the extension of the Voyant 5mm Fusion device's shelf life from 18 months to 36 months. The fundamental technological features and intended use of each subject device are the same as its predicate device.

Discussion of Performance Testing:

The FDA guidance documents *Premarket Notification (510(k)) Submissions for Electrosurgical Devices for General Surgery (2020)*, *Premarket Notification (510(k)) Submissions for Bipolar Electrosurgical Vessel Sealers for General Surgery (2016)*, and *Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices (2005)* were considered in evaluating the subject devices' electrical, software, and functional capabilities. The tests addressed below were utilized to demonstrate safety and efficacy of the subject devices and substantial equivalence to the respective predicate devices.

EMC, Electrical Safety, and Mechanical Testing

Both the Voyant Open Fusion and Voyant 5mm Fusion devices were designed and evaluated in accordance with relevant standards of the IEC 60601 series for electromagnetic compatibility and electrical testing and met all acceptance criteria. The EMC and Electrical Safety testing was conducted in K162676 for Voyant Open Fusion device, and in K141288 and K172624 for Voyant 5mm Fusion device.

Simulated repeated-use testing was conducted to verify the continued performance of each subject device over multiple device activations. The results of the studies demonstrated that both subject devices met the predetermined acceptance criteria.

System Testing

The following testing was performed using each of the subject devices in comparison to its respective predicate:

- Burst pressure testing using vessels representative of the devices' indications. These vessels were sealed, and the burst pressure of each vessel was recorded.
- Thermal spread testing to evaluate the thermal damage produced by the subject and predicate devices.

The results of these tests demonstrated that both subject devices met the predetermined acceptance criteria and each subject device is substantially equivalent to its respective predicate device with respect to these test endpoints.

Animal Testing

A chronic survival study was performed using large porcine animal models to evaluate long-term seal quality, devices' performance, and the potential for an adverse effect on adjacent structures. Vessels representative of the devices' indications were sealed and evaluated for hemostasis and signs of hematoma. The results of the study demonstrated that both subject devices met the predetermined acceptance criteria.

Software Verification

Unit, integration, and system level software testing were conducted to evaluate the design, implementation, and performance of the devices' software scripts.

Conclusion:

Results of performance testing demonstrated that both the subject Voyant Open Fusion and subject Voyant 5mm Fusion devices, with the updated software scripts, are substantially equivalent to the predicate Voyant Open Fusion device and predicate 5mm Open Fusion device, respectively, for requested intended use.