October 11, 2018

Applied Medical Resources Corp.
Mr. Andrew Nguyen
Regulatory Affairs Specialist I
22872 Avenida Empresa
Rancho Santa Margarita, California 92688

Re: K182244
Trade/Device Name: Voyant Electrosurgical Generator
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical Cutting and Coagulation Device and Accessories
Regulatory Class: Class II
Product Code: GEI
Dated: September 24, 2018
Received: September 25, 2018

Dear Mr. 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. 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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

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,

FDA

Long H. Chen -S
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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)*

K182244

Device Name
Voyant Electrosurgical Generator

Indications for Use *(Describe)*
The Voyant electrosurgical generator is indicated for use with Voyant devices in open and laparoscopic surgical procedures where the electrosurgical ligation of vessels or tissue bundles is desired.

Note: For indications specific to each Voyant device used with the Voyant generator, refer to each device's Instructions for Use (IFU).

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.

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: 17 August 2018

Trade Name: Voyant® Electrosurgical Generator

Common Name: Electrosurgical Generator

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

Legally Marketed Device: Voyant® Electrosurgical Generator
510(k)#: K141288
Product Code: GEI

Device Description: The Applied Medical Voyant Electrosurgical Generator (ESG) is a tabletop radiofrequency (RF) power supply designed for use in electrosurgery. It operates outside the sterile field and is equipped with a receptacle for Voyant hand piece devices. The ESG enclosure is constructed of various metals and polymers and houses all electrical hardware and software components. The front panel features an LCD and buttons for the navigation, adjustment, and selection of ESG settings.

Intended Use: The Voyant electrosurgical generator is indicated for use with Voyant devices in open and laparoscopic surgical procedures where the electrosurgical ligation of vessels or tissue bundles is desired.

Summary of Technological Characteristics between Subject and Predicate Devices:

The subject and predicate generators are technologically similar in that both are reusable, electrically isolated, microprocessor controlled power supplies that deliver radiofrequency (RF) energy to connected Applied Medical Voyant hand piece devices for the sealing of vessels and tissue bundles. Both devices operate outside of the sterile field and support compatible devices that operate within the sterile field. They are made of similar materials (i.e. metals and polymers) and have a graphical user interface that displays information to the user regarding device connection, seal cycle status, and alarm conditions. It also contains menu screens and option settings that can be navigated using the soft button keys.

The subject device features a number of upgrades, including a reduction in overall size, a redesigned device connection receptacle, an increased maximum voltage limit, and an enhanced system maintenance verification test.

The overall performance of the subject and predicate generators are substantially equivalent as the sealing algorithms of the Voyant system are not affected by the aforementioned upgrades.

Discussion of Performance Testing:

The FDA guidance documents *Premarket Notification (510(k)) Submissions for Electrosurgical Devices for General Surgery (2016), 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 device's electrical, software, 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 and Electrical Safety Testing

The Voyant ESG was designed and evaluated in accordance with relevant standards of the IEC 60601 series for electromagnetic compatibility and electrical testing.

System Testing

Burst pressure testing was conducted using the subject and predicate Voyant ESGs in conjunction with each legally marketed Voyant hand piece device. The results of the study demonstrated that the subject generator has substantially equivalent performance to the predicate generator with each Voyant hand piece.

Thermal spread testing was performed to evaluate the thermal spread damage produced by the subject and predicate Voyant ESGs when coupled with each legally marketed Voyant hand piece device. Analysis of the measurements demonstrated that the subject generator has substantially equivalent performance to the predicate generator with each Voyant hand piece.

Clinical

No chronic survival 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

Software functional testing was performed on each software subsystem to verify that all software requirements were met.

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

Conclusion:

The subject Voyant Electrosurgical Generator is substantially equivalent in performance to the predicate Voyant Electrosurgical Generator 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.