October 31, 2025

Applied Medical Resources Corporation
Derek Greene
Associate Principal Specialist
22872 Avenida Empresa
Rancho Santa Margarita, California 92688

Re: K252412
Trade/Device Name: Voyant® Electrosurgical Generator (EA030/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: October 8, 2025
Received: October 8, 2025

Dear Derek Greene:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device"

(https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

Colin K. Chen -S

Digitally signed by Colin K. Chen -S
Date: 2025.10.31 11:47:26 -04'00'

Colin Kejing Chen
Acting 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

Indications for Use

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.	K252412

Please provide the device trade name(s).

Voyant® Electrosurgical Generator (EA030/Electrosurgical Generator)

Please provide your Indications for Use below.

Advanced Bipolar: The Voyant electrosurgical generator is indicated for use with advanced bipolar Voyant devices in open and minimally invasive procedures where the ligation of vessels up to and including 7mm in diameter and 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).

Monopolar/Bipolar: Intended to provide energy to standard monopolar and bipolar surgical accessories.

Please select the types of uses (select one or both, as applicable).

- ☒ Prescription Use (Part 21 CFR 801 Subpart D)
- ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

510(k) #: K252412

510(k) Summary

Prepared on: 2025-10-07

Contact Details

21 CFR 807.92(a)(1)

Applicant Name	Applied Medical Resources Corporation
Applicant Address	22872 Avenida Empresa Rancho Santa Margarita CA 92688 United States
Applicant Contact Telephone	949-713-8009
Applicant Contact	Dr. Derek Greene
Applicant Contact Email	derek.greene@appliedmedical.com

Device Name

21 CFR 807.92(a)(2)

Device Trade Name	Voyant® Electrosurgical Generator (EA030/Electrosurgical Generator)
Common Name	Electrosurgical cutting and coagulation device and accessories
Classification Name	Electrosurgical, Cutting & Coagulation & Accessories
Regulation Number	878.4400
Product Code(s)	GEI

Legally Marketed Predicate Devices

21 CFR 807.92(a)(3)

Predicate #	Predicate Trade Name (Primary Predicate is listed first)	Product Code
K151649	Valleylab™ FT10 Electrosurgical Platform	GEI
K182244	Voyant® Electrosurgical Generator	GEI

Device Description Summary

21 CFR 807.92(a)(4)

The Applied Medical Voyant Electrosurgical Generator (EA030) is a reusable, electrically isolated, microprocessor-controlled power supply intended to deliver radiofrequency (RF) energy for electrosurgical applications. It provides energy output to compatible monopolar, bipolar, and Voyant advanced bipolar instruments for the cutting, coagulation, and sealing of vessels and tissue bundles. The Voyant EA030 operates outside the sterile field and interfaces with active surgical instruments that operate within the sterile field. The system comprises integrated mechanical, electrical, and software components, constructed from various metals and polymers. It features a front-panel LCD touchscreen that enables users to view, navigate and adjust operating modes and system settings.

Voyant EA030 is designed to function as part of a system that includes optional accessories such as active devices, footswitches, and patient return electrodes. These components work together to ensure safe and effective energy delivery during surgical procedures.

Intended Use/Indications for Use

21 CFR 807.92(a)(5)

Advanced Bipolar: The Voyant electrosurgical generator is indicated for use with advanced bipolar Voyant devices in open and minimally invasive procedures where the ligation of vessels up to and including 7mm in diameter and 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).

Monopolar/Bipolar: Intended to provide energy to standard monopolar and bipolar surgical accessories.

Indications for Use Comparison

21 CFR 807.92(a)(5)

The indications for use statements for the subject device—Voyant Electrosurgical Generator (EA030) and its predicates, Valleylab FT10 Electrosurgical Platform (FT10) (primary predicate) and Voyant Electrosurgical Generator Gen 2 (EA020) (secondary predicate), exhibit minor differences in format and specificity. However, all three devices are classified as "tool type" devices and share the same core intended use: to deliver energy to compatible handpieces for electrosurgical procedures.

The Valleylab FT10 includes handpiece-specific indications within its generator labeling, whereas the Voyant EA030 and Voyant EA020 list only generator-level indications. Handpiece-specific indications for the Voyant EA030 are provided separately in the Instructions for Use (IFUs) for each compatible handpiece. This difference in labeling approach does not reflect a change in clinical functionality or intended use. For both the subject and primary predicate device, monopolar and bipolar energy outputs are selected by the operating surgeon and applied to tissues deemed appropriate for electrosurgery. For the subject and both predicate devices, Advanced bipolar energy is used in conjunction with compatible handpieces to seal vessels up to 7 mm in diameter and tissue bundles. There are no differences in the intended patient population across the three devices. All are intended for use in adult patients, who are deemed suitable candidates for electrosurgical procedures by physicians.

In summary, despite minor differences in labeling format, the Voyant EA030, Valleylab FT10, and Voyant EA020 share the same general intended use. These differences do not raise new or unresolved clinical questions regarding the safety or effectiveness of the subject device.

Technological Comparison

21 CFR 807.92(a)(6)

The subject device, Voyant EA030, and the primary predicate device, Valleylab FT10, both support monopolar, bipolar, and advanced bipolar modalities. The secondary predicate, Voyant EA020, is included to establish substantial equivalence specifically for the advanced bipolar functionality.

The Voyant EA030 and Valleylab FT10 share the following core technological characteristics:
- Support for monopolar, bipolar, and advanced bipolar energy modalities
- Environmental compatibility with patient return electrodes, footswitches, and active handpieces
- Electrically isolated design with microprocessor control
- User interface with touchscreen navigation
- Internal power supply
- RF energy delivery for monopolar (pure cut, blend cut) and bipolar (low, medium, high) functions

Technological Differences
Notably, the following differences exist between the subject and primary predicate devices:
- RF Functionality: The Valleylab FT10 includes additional RF modes not present in the Voyant EA030. These additional modes are not required for the subject device to fulfill its intended use.
- Device Identification: The Valleylab FT10 uses RFID technology to identify advanced bipolar handpieces, with associated software stored in the generator. In contrast, the Voyant EA030 identifies handpieces via a plug-in connection, with the software script embedded in the handpiece itself.
- Network Connectivity: The Valleylab FT10 supports network connectivity, whereas the Voyant EA030 operates without any network connectivity.
- Technical Specifications: Minor differences exist in specific technical values (e.g., output power ranges, impedance thresholds). However, all specifications fall within the typical range for electrosurgical generators and comply with applicable electrical safety standards.

The Voyant EA030 and Voyant EA020 share the same technological characteristics for advanced bipolar functionality and are both compatible with Voyant advanced bipolar handpieces, ensuring equivalent performance and safety.

In conclusion, the technological differences between the subject and predicate devices do not raise new questions regarding safety or effectiveness. The Voyant EA030 performs the same core functions as both predicate devices.

Non-Clinical and/or Clinical Tests Summary & Conclusions

21 CFR 807.92(b)

Non-Clinical Testing:
The subject device, Voyant Electrosurgical Generator Gen 3, (EA030), was evaluated in accordance with the following 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)
- Content of Premarket Submissions for Device Software Functions (2023)

These documents guided the assessment of the device's electrical safety, software functionality, and performance characteristics. No chronic survival or clinical studies were required to demonstrate the safety and effectiveness of the subject device for this premarket submission.

The following non-clinical tests were conducted to support substantial equivalence:
• Electromagnetic Compatibility (EMC) and Immunity Testing
Voyant EA030 was tested in accordance with applicable standards from the IEC 60601 series to ensure compliance with electromagnetic compatibility and immunity requirements. (Refer to Section: EMC, Wireless, Electrical, Mechanical, and Thermal Safety.)

• Electrical, Mechanical, and Thermal Safety Testing
Voyant EA030 was evaluated for electrical, mechanical, and thermal safety under the IEC 60601 series. (Refer to Section: EMC, Wireless, Electrical, Mechanical, and Thermal Safety.)

• Power Output and Waveform
Experimental values determined for the subject device Voyant EA030 fell within the ranges of both predicate devices, Voyant EA020 and Valleylab FT10. For each monopolar and bipolar function present on the subject device, the ranges provided by the subject device are similar/identical to the predicate devices and the output tolerances were verified as part of IEC 60601 testing.

• System Testing – Advanced Bipolar Functionality
Burst Pressure Testing: Conducted using subject device Voyant EA030 and predicate Voyant EA020 in conjunction with each legally marketed Voyant advanced bipolar handpiece. Results demonstrated equivalent vessel sealing performance.
Thermal Spread Testing: Performed to compare thermal spread between the Voyant EA030 and Voyant EA020 when used with each compatible handpiece. Results confirmed comparable local tissue effects.

• Software Verification and Validation
Software testing included unit, integration, and system-level evaluations to verify that all software requirements were met. Testing confirmed the correct implementation and performance of embedded software scripts. (Refer to Section: Software, Firmware, & Cybersecurity Interoperability.)

Clinical testing:
Not Applicable. Clinical data were not required to support the safety or effectiveness of the subject device.

Conclusion:
The non-clinical performance data demonstrate that the subject device Voyant EA030 performs equivalent to the predicate Valleylab FT10 for monopolar and bipolar power output and waveform characteristics. Voyant EA030 performs equivalent to Voyant EA020 with respect to vessel sealing performance and local tissue effects. Therefore Voyant EA030 performs the same intended use as predicate devices without raising new issues of safety or effectiveness.