November 4, 2025

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

Re: K252740
Trade/Device Name: Voyant® Open Fusion Device (EB240/Open Fusion)
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: 2025.11.04 09:12:00 -05'00'

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.	K252740

Please provide the device trade name(s).

Voyant® Open Fusion Device (EB240/Open Fusion)

Please provide your Indications for Use below.

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.

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) #: K252740

510(k) Summary

Prepared on: 2025-10-08

Contact Details

21 CFR 807.92(a)(1)

Applicant Name	Applied Medical Resources Corp.
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® Open Fusion Device (EB240/Open Fusion)
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
K201212	Voyant® Open Fusion Device	GEI

Device Description Summary

21 CFR 807.92(a)(4)

Voyant® Open Fusion is an advanced bipolar instrument that uses radiofrequency (RF) energy, provided by the Voyant Electrosurgical Generator (Voyant ESG), 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. Once the tissue is fused, the sealed tissue may be divided with a user-actuated blade to transect the tissue at the seal site.

The Voyant Open Fusion is comprised of three sections: jaws, shaft, and handle (including the cord and device plug). The subject device features a curved jaw with a tapered jaw design. The updated tapered jaw design does not change the device's intended function or user interface. The pistol-grip style handle features a knob, fuse button, trigger, and blade lever. The knob enables 180° rotation of Voyant Open Fusion device jaws. The trigger opens and closes the device jaws and can latch when the jaws are in the closed position. Squeezing the trigger again will release the latch and allow the jaws to open. The fuse button on the back of the handle activates RF energy. When the fuse button is pressed and held for the full seal cycle, RF output will automatically stop upon a complete seal, an audible tone will be heard and a message is displayed on the Voyant ESG screen. If the user releases the button prior to seal completion, RF output will be interrupted, an alarm tone will be heard and a message is displayed on the ESG screen. To transect the tissue, the user pulls the blade lever while the jaws are latched in the closed position.

The device connects to the Voyant ESG via a device plug and cord. The cord and device plug are attached to the device handle. The cord facilitates the transfer of RF energy from the ESG, through the handle, along the shaft, and to the jaws. The device plug has a distinct shape which enables a proprietary connection to the Voyant ESG.

Intended Use/Indications for Use

21 CFR 807.92(a)(5)

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.

Indications for Use Comparison 21 CFR 807.92(a)(5)

The intended use of the subject device is the same as the predicate device. There are no changes made to the indications for use of the subject device.

Technological Comparison 21 CFR 807.92(a)(6)

The subject and predicate devices are single-use, electrosurgical handpiece devices designed to deliver RF energy to vessels and tissue captured between its jaws for tissue fusion. Both devices feature a pistol-grip style handle with a trigger for jaw closure and a button for energy activation, a rotation knob to rotate the jaws, as well as a blade lever for tissue transection once fusion is completed. The subject device maintains all primary features of the predicate device.

Software script has been updated to accommodate design changes to the jaws as well as improve the efficiency of the tissue fusion cycle; both the Voyant Open Fusion subject and predicate devices' scripts have a similar structure in terms of voltage profile and seal cycle stages. Physical changes to the device since last clearance include updates in shaft diameter, tip configuration, seal dimensions, blade stroke, rated accessory voltage, storage conditions, and sterilization method. However, the fundamental technological features and intended use of the subject device remain the same as the predicate device.

Non-Clinical and/or Clinical Tests Summary & Conclusions 21 CFR 807.92(b)

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 Content of Premarket Submissions for Device Software Functions (2023) were considered in evaluating the subject device's electrical, software, and functional capabilities.

EMC, Electrical and Mechanical Safety Testing:
The predicate Voyant Open Fusion device was designed and evaluated in accordance with relevant standards of the IEC 60601 series for electromagnetic compatibility and electrical testing and met all acceptance criteria. Additional safety testing was done on the subject device and met all acceptance criteria.

System Testing:
- Burst pressure testing was performed using vessels representative of the devices' indications. These vessels were sealed, and the burst pressure of each vessel were compared between the subject and predicate devices. For each of these vessel categories, the subject device achieved equivalent or greater mean burst pressure compared to the predicate and met all acceptance criteria.
- Thermal spread testing was performed to evaluate the spread of thermal damage along the vessels produced by the subject and predicate devices. Results confirmed there is no statistically significant difference between the subject and predicate thermal spread and met all acceptance criteria.

Animal Testing:
A chronic survival study was performed using large porcine animal models to evaluate long-term seal quality, device 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. Results confirmed no indication of hematoma at necropsy and structural integrity of all sealed vessels remained intact without abnormalities and met all acceptance criteria.

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

Conclusion:
The subject Voyant Open Fusion device met all predetermined device requirements (acceptance criteria) thereby establishing the device as substantially equivalent in performance and safety to the predicate device with respect to the intended use (i.e. vessel sealing performance and local tissue effects) and does not raise any new issues of safety and efficacy.