



December 16, 2021

Applied Medical Resources Corporation
Blake Stacy
Senior Regulatory Affairs Analyst
22872 Avenida Empresa
Rancho Santa Margarita, California 92688

Re: K202818

Trade/Device Name: Voyant Fine Fusion Device (EB230)

Regulation Number: 21 CFR 878.4400

Regulation Name: Electrosurgical Cutting and Coagulation Device and Accessories

Regulatory Class: Class II

Product Code: GEI

Dated: November 18, 2021

Received: November 19, 2021

Dear Blake Stacy:

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

Indications for Use

Submission Number (if known)

K202818

Device Name

Voyant Fine Fusion (EB230)

Indications for Use (Describe)

The Voyant Fine Fusion device is a bipolar, electrosurgical device indicated for use with the Voyant electrosurgical generator in open procedures, including head and neck 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: 13 December 2021

Trade Name: Voyant® Fine 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® Fine Fusion Device
510(k)#: K153017
Produce Code: GEI

Device Description: The Voyant Fine Fusion device is an advanced bipolar instrument that uses RF energy, provided by the Voyant Electrosurgical Generator (K182244), 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 Fine Fusion device is a bipolar, electrosurgical device intended for use with the Voyant Electrosurgical Generator to seal and divide vessels and tissues bundles.

Indications for Use: The Voyant Fine Fusion device is a bipolar, electrosurgical device indicated for use with the Voyant electrosurgical generator in open procedures, including head and neck 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 and predicate devices are single-use, electrosurgical hand piece devices designed to deliver RF energy to vessels and tissue captured between its jaws for tissue fusion. Both devices feature a scissor-grip style handle and a button for energy activation. The devices are equipped with a mechanical, user-actuated blade for the division of sealed tissue.

The subject device design is the same as the predicate, with the exception of the change in software of the device, design of the device plug, and extension of the device's shelf life from 6 months to 36 months. The fundamental technological features, and intended use of the subject device are the same as the 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 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, Electrical Safety, and Mechanical Testing

The Voyant Fine 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.

Simulated repeated-use testing was conducted to verify the continued performance of the device over multiple device activations. The passing result of the study conducted on the predicate device are sufficient for the subject device, and need not be repeated to demonstrate mechanical performance of the subject device.

System Testing

The following testing was performed using the subject device in comparison to the 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 spread damage produced by the subject and predicate devices.

Analysis of the results of these tests demonstrated that the subject device met the predetermined acceptance criteria and is substantially equivalent to the predicate device with respect to these test endpoints.

Animal Testing

An acute animal study was conducted using large porcine animal models to examine the thermal damage produced by the subject and predicate devices. Cellular viability was analyzed using functional staining techniques. Samples were sent to a qualified histopathology laboratory for evaluation.

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 by a qualified histopathologist for hemostasis and signs of hematoma. The results of the study demonstrated that the subject device met the predetermined acceptance criteria.

The results of both the acute and chronic animal studies demonstrate safety and efficacy of the subject device, and confirm its substantially equivalent performance to the predicate device.

Software Verification

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

Biocompatibility

In accordance with ISO 10993-1 and the 2016 FDA guidance, *Use of International Standard ISO 10993-1, "Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process"*, the subject device met all acceptance criteria for the following biocompatibility evaluations:

- Cytotoxicity (per ISO 10993-5)
- Intracutaneous Reactivity (per ISO 10993-10)
- Sensitization (per ISO 10993-10)
- Acute Systemic Toxicity (per ISO 10993-11)

Conclusion:

The subject Voyant Fine Fusion device with the updated software script is substantially equivalent in performance to the predicate Voyant Fine 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. The subject device is as safe and effective as the predicate device for the intended use.