



**VOYANT**<sup>TM</sup>  
INTELLIGENT ENERGY SYSTEM

**Applied**  
Medical 



# Voyant System

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# Voyant

## Intelligent Energy System



The Voyant advanced bipolar system collects information about the nature of the tissue within its jaws, rapidly and constantly measures tissue as the energy is applied, and adjusts to provide the optimal amount of energy throughout the seal cycle to create a permanent, fused seal.

Sold in over **65 countries**  
 Shipped over **1,500,000 units**  
 Shipped to over **4,200 facilities**

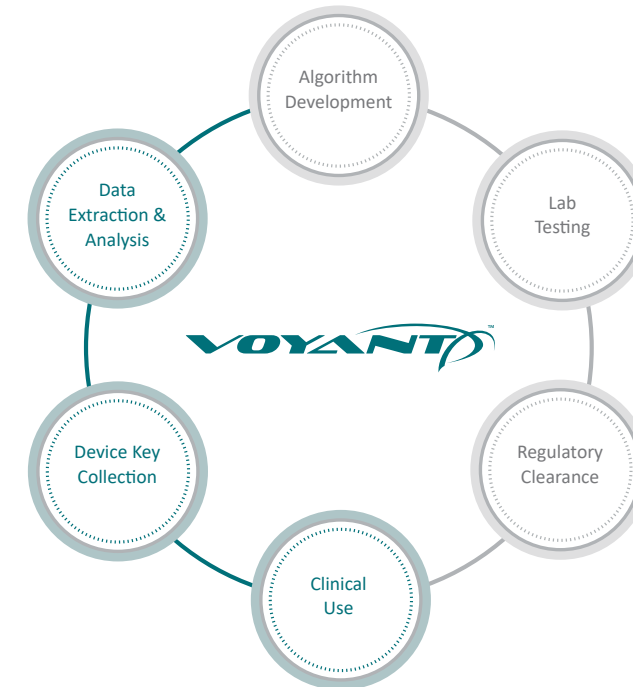
### Device Key with Embedded Intelligence

Optimizes energy delivery for procedural needs.  
 Collects and stores activation data for the purpose of *learning from live human tissue*.  
 Enables efficient implementation of algorithm updates and delivery of the most advanced technology with each handpiece.



# Voyant

## System Development Cycle



### Differentiation Through Clinical Learning

Intelligence is defined as the ability to learn. Unlike other devices that rely on lab data for vessel-sealing algorithm development, the Voyant Intelligent Energy system has the ability to accelerate learning from clinical use on live human tissue. Through gaining an understanding of product use, Applied Medical continues to advance the Voyant technology to better meet specific clinical needs.

### Intelligence Gathering

The Voyant device key connected to each handpiece stores activation data from each vessel or tissue bundle sealed throughout the procedure. By partnering with hospitals and surgeons to collect device keys, Applied Medical scientists and engineers are able to analyze the data to further optimize energy delivery.

### Benefits of Voyant System Intelligence

The Voyant system's continual energy optimization means Applied Medical can make each activation more efficient, resulting in superior hemostasis,\* faster seal times,\* minimal lateral thermal spread,† and less tissue adherence.\* The benefits of the Voyant system's efficient sealing can be easily recognized through seal cycles that are less than one second.\* In addition, continual energy optimization means the technology has the potential to address energy delivery for even the most challenging tissue types.

\* Based on an internal test report from April 2020, comparing the current algorithm to the previous algorithm, and internal benchtop testing reports from February and March 2021.

† Based on a third-party H&E histological analysis performed in April 2020.

# Voyant

## Maryland Fusion Device with Single-Step Activation

### Unrestricted Shaft Rotation

Allows for continuous, 360-degree rotation to facilitate accurate jaw placement.



### Single-Action, Curved, Tapered Jaw with Dissecting Tips

Aids in tracking the contour of anatomical structures, visualizing the tips of the jaw, and optimizing control during tissue dissection.

### Blade Lever

Transects tissue with a mechanical blade.



### Spring-Loaded Handle Lever with Inset Fuse Activation Button

Increases user efficiency by reducing the steps required for energy activation. Opens automatically when released.

### Voyant Maryland Fusion Device with Single-Step Activation

Model	Modality	Maximum Vessel Diameter	Shaft Length	Jaw Style	Handle Style	Trocar Compatibility	Seal Length	Cut Length	Jaw Shape	Shaft Rotation
EB212	Advanced bipolar	7mm	37cm	Single action	Single-step activation	5mm or larger	20mm	18mm	Curved, with dissecting tips	360°
EB213	Advanced bipolar	7mm	44cm	Single action	Single-step activation	5mm or larger	20mm	18mm	Curved, with dissecting tips	360°
EB214	Advanced bipolar	7mm	23cm	Single action	Single-step activation	5mm or larger	20mm	18mm	Curved, with dissecting tips	360°

# Voyant

## Maryland Fusion Device

### Unrestricted Shaft Rotation

Allows for continuous, 360-degree rotation to facilitate accurate jaw placement.



### Single-Action, Curved, Tapered Jaw with Dissecting Tips

Aids in tracking the contour of anatomical structures, visualizing the tips of the jaw, and optimizing control during tissue dissection.

### Blade Lever

Transects tissue with a mechanical blade.

### Fuse Activation Button

Activates energy delivery.



### Spring-Loaded Handle Lever with Latch

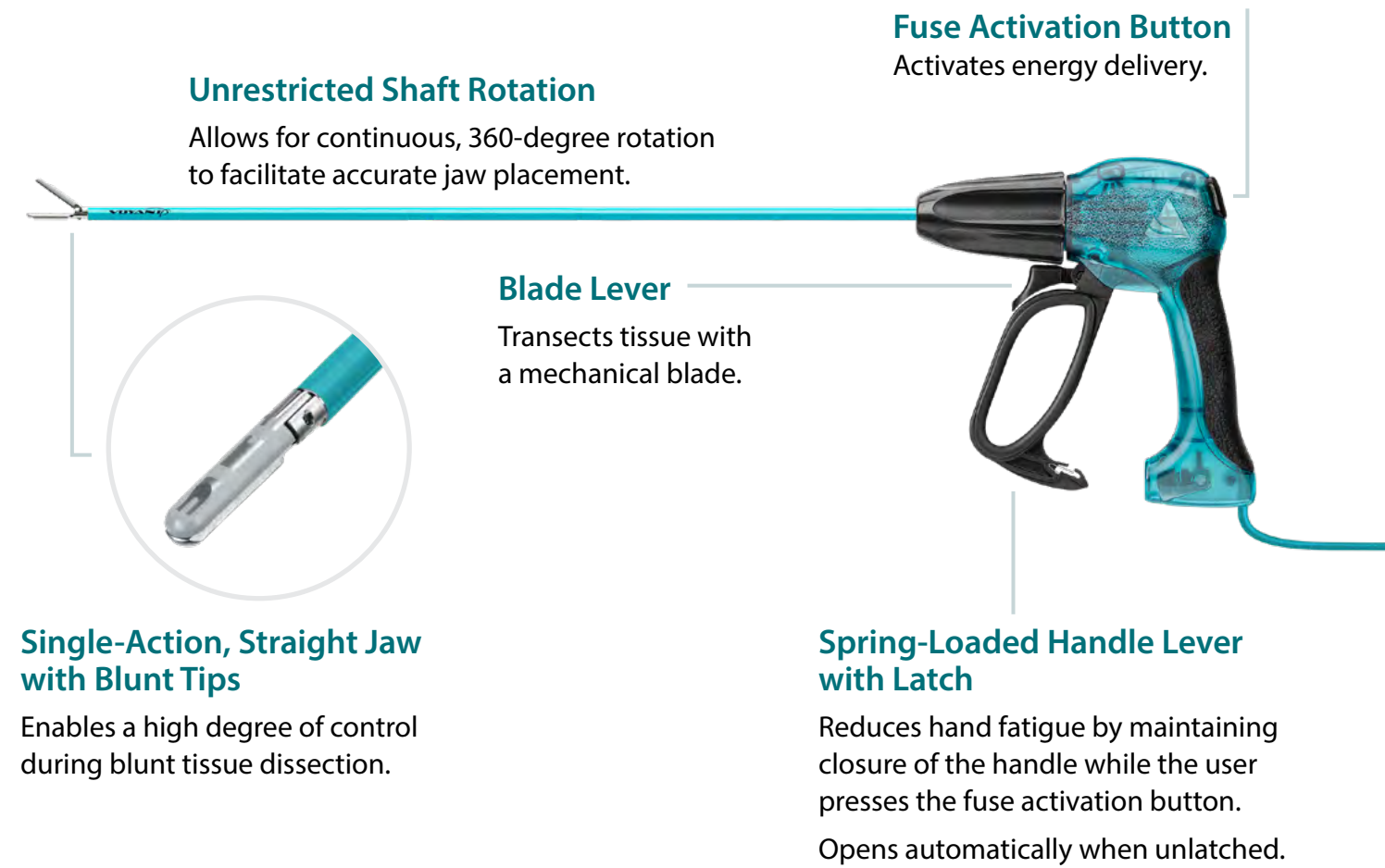
Reduces hand fatigue by maintaining closure of the handle while the user presses the fuse activation button. Opens automatically when unlatched.

### Voyant Maryland Fusion Device

Model	Modality	Maximum Vessel Diameter	Shaft Length	Jaw Style	Handle Style	Trocar Compatibility	Seal Length	Cut Length	Jaw Shape	Shaft Rotation
EB215	Advanced bipolar	7mm	37cm	Single action	Latching	5mm or larger	20mm	18mm	Curved, with dissecting tips	360°
EB216	Advanced bipolar	7mm	44cm	Single action	Latching	5mm or larger	20mm	18mm	Curved, with dissecting tips	360°
EB217	Advanced bipolar	7mm	23cm	Single action	Latching	5mm or larger	20mm	18mm	Curved, with dissecting tips	360°

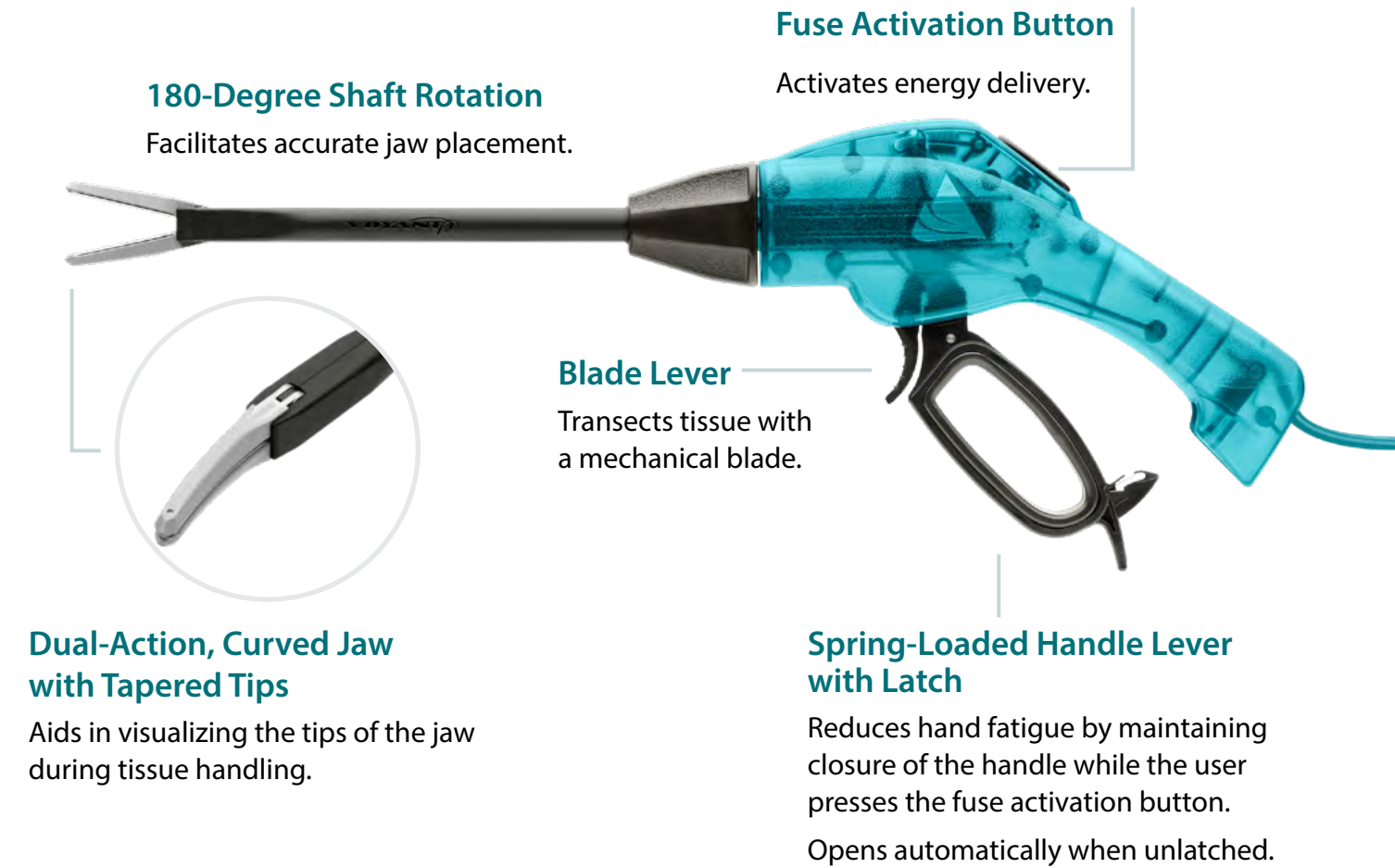
# Voyant

## 5mm Fusion Device



# Voyant

## Open Fusion Device



### Voyant 5mm Fusion Device

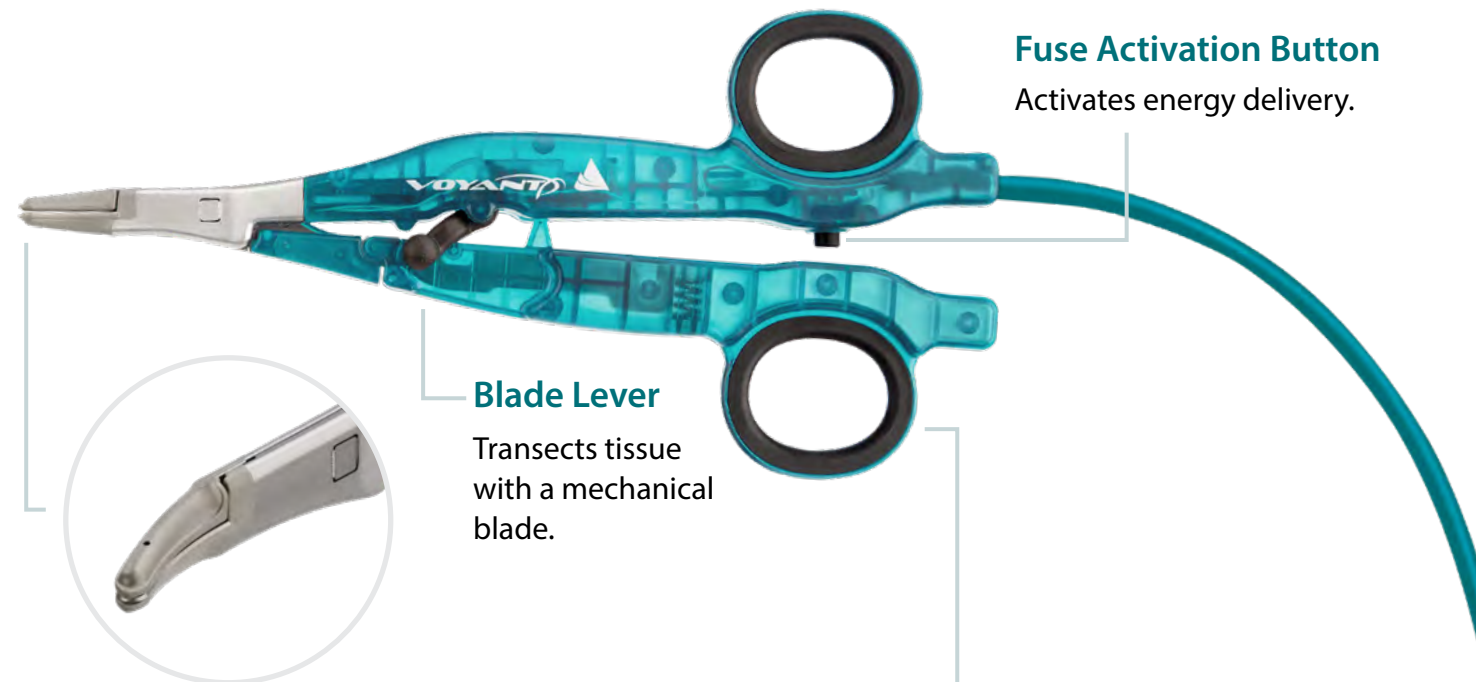
Model	Modality	Maximum Vessel Diameter	Shaft Length	Jaw Style	Handle Style	Trocar Compatibility	Seal Length	Cut Length	Jaw Shape	Shaft Rotation
EB210	Advanced bipolar	7mm	37cm	Single action	Latching	5mm or larger	20mm	18mm	Straight, with blunt tips	360°
EB211	Advanced bipolar	7mm	44cm	Single action	Latching	5mm or larger	20mm	18mm	Straight, with blunt tips	360°

### Voyant Open Fusion Device

Model	Modality	Maximum Vessel Diameter	Shaft Length	Jaw Style	Seal Length	Cut Length	Jaw Shape	Shaft Rotation
EB240	Advanced bipolar	7mm	20cm	Dual action	38mm	36mm	Curved, with tapered tips	180°

# Voyant

## Fine Fusion Device



**Blade Lever**  
Transects tissue with a mechanical blade.

**Fuse Activation Button**  
Activates energy delivery.

**Ring Handle**  
Provides an ergonomic, scissor-style grip.

**Dual-Action, Curved Jaw with Dissecting Tips**  
Aids in tracking the contour of anatomical structures, visualizing the tips of the jaw, and optimizing control during fine tissue dissection.

### Voyant Fine Fusion Device

Model	Modality	Maximum Vessel Diameter	Device Length	Jaw Style	Seal Length	Cut Length	Jaw Shape
EB230	Advanced bipolar	7mm	19.3cm	Dual action	17mm	15mm	Curved, with dissecting tips

# Voyant EVALUATION AGREEMENT

PREVIEW	EVALUATION PERIOD	
Start Date	Scheduled Start Date	Scheduled End Date

We have reviewed and understand the clinical evaluation process. The goal of this evaluation is to collect objective clinical feedback about the functionality and acceptability of the Applied Medical products and thereby provide the basis for support to contract the Applied Medical product.

Product shall be purchased for the agreed-upon length of the evaluation period at the prices set forth in the attached Exhibit A. Returns associated with this evaluation will not incur a restocking fee and must be received by Applied Medical 10 business days after the end date set forth above. Thereafter, Applied Medical reserves the right to limit or decline these special terms for returns, exchanges or credits, and its current return policy would apply.

\_\_\_\_\_ (quantity) EA030 and \_\_\_\_\_ (quantity) EA020 Voyant electrosurgical generator(s) will be provided for use during the evaluation process as outlined in our Equipment Right-to-Use Terms and Conditions set forth at <https://www.appliedmedical.com/Legal/TermsOfSale>. Per existing regulatory guidance, the time period for any evaluation of capital equipment shall not exceed the amount of time reasonably necessary to allow for an adequate evaluation, given the circumstances of the evaluation, but in no event shall it be longer than 90 days. It is agreed that at the end of the evaluation, Customer will either stop using the capital equipment or purchase handpieces at a minimum rate to comply with regulatory guidance. If the generators continue to be used after the evaluation, refer to the Equipment Right-to-Use Terms and Conditions outlined above.

ACCOUNT OR HEALTH SYSTEM	ACCOUNT NUMBER(S) (LIST ALL THAT APPLY)

CUSTOMER

APPLIED MEDICAL

Signature

Signature

Printed Name

Printed Name

Title

Title

Email Address

Date

Date

# Voyant

## EA030 Electrosurgical Generator



### All-in-One System

The EA030 Voyant electrosurgical generator combines monopolar and standard bipolar energy modalities with the reliable hemostasis of Voyant advanced bipolar energy – all in one system.

### Seamless Software Updates

The Voyant Intelligent Energy system delivers the latest technology through the device key, eliminating the need for generator software updates.

### Enhanced Safety and Reliability

Calibration and verification checks are performed automatically during every startup, minimizing preventive maintenance.

### Easy Preventive Maintenance

Output verification testing can be run at the touch of a button, the results being displayed on-screen.

### Clinician-Driven Design

Developed in collaboration with surgeons and nurses, the EA030 generator features user-friendly navigation and clear tones.

### Intuitive Interface

Automatic device and accessory recognition allow for quick setup – simply turn on the generator, connect a device, adjust the settings as needed, and it's ready to use.

### EA030 Voyant Electrosurgical Generator

Model	Description	Modalities	Product Size and Weight	Ports
EA030	Voyant electrosurgical generator	Monopolar, standard bipolar, and advanced bipolar	47.6cm x 38.1cm x 18.5cm (11.3kg)	5
EA031	Monopolar footswitch	Monopolar	32.3cm x 18.8cm x 4.8cm (0.726kg)	N/A
EA032	Bipolar footswitch	Bipolar	15cm x 17.5cm x 4.4cm (0.354kg)	N/A
EX150	Voyant cart	N/A	76.12cm x 49.00cm x 101.22cm (30.20kg)	N/A

# Voyant

## EA020 Electrosurgical Generator



### Advanced Energy

The EA020 Voyant electrosurgical generator is an advanced bipolar generator compatible with all Voyant devices.

### Seamless Software Updates

The Voyant Intelligent Energy system delivers the latest technology through the device key, eliminating the need for generator software updates.

### Enhanced Safety and Reliability

Calibration and verification checks are performed automatically during every startup, minimizing preventive maintenance.

### Easy Preventive Maintenance

Output verification testing can be run at the touch of a button, the results being displayed on-screen.

### Sleek and Simple Design

The Voyant generator boasts a small profile and a user interface that is easy to use.

### Plug and Play System

Simply turn on the generator and connect a Voyant device. The system is ready to use!

### EA020 Voyant Electrosurgical Generator

Model	Description	Modality	Product Size and Weight	Ports
EA020	Voyant electrosurgical generator	Advanced bipolar	35.1cm x 30.5cm x 11.3cm (6.6kg)	1
EX150	Voyant cart	N/A	76.12cm x 49.00cm x 101.22cm (30.20kg)	N/A



October 14, 2022

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

Re: K222284  
Trade/Device Name: Voyant Maryland Fusion device with Single-Step Activation (EB212, EB213, EB214)  
Regulation Number: 21 CFR 878.4400  
Regulation Name: Electrosurgical Cutting And Coagulation Device And Accessories  
Regulatory Class: Class II  
Product Code: GEI  
Dated: September 15, 2022  
Received: September 16, 2022

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

U.S. Food & Drug Administration  
10903 New Hampshire Avenue  
Silver Spring, MD 20993  
[www.fda.gov](http://www.fda.gov)

K222284 - Blake Stacy

Page 2

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](mailto:DICE@fda.hhs.gov)) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

  
**Colin K. Chen -S**

for

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



April 8, 2020

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

Re: K200598

Trade/Device Name: Voyant Maryland 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: March 9, 2020  
Received: March 9, 2020

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](#).

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K200598 - Blake Stacy

Page 2

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](mailto:DICE@fda.hhs.gov)) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Long H. Chen -S

Digitally signed by Long H. Chen  
Date: 2020.04.08 09:46:19 -04'00'

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



December 20, 2019

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

Re: K193292

Trade/Device Name: Voyant 5mm Fusion Device, Voyant Maryland 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: November 27, 2019  
Received: November 27, 2019

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

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K193292 - Blake Stacy

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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](mailto:DICE@fda.hhs.gov)) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

**Cal F. Rabang -S**

For:  
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



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](#).

K252740 - Derek Greene

Page 2

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](mailto: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

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

K202818 - Blake Stacy

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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](mailto:DICE@fda.hhs.gov)) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Long H. Chen -S  
Digitally signed by Long H. Chen  
-S  
Date: 2021.12.16 07:17:14 -05'00'

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



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"

U.S. Food & Drug Administration  
10903 New Hampshire Avenue  
Silver Spring, MD 20993  
[www.fda.gov](http://www.fda.gov)

K252412 - Derek Greene

Page 2

(<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/combo-products/guidance-regulatory-information/postmarketing-safety-reporting-combo-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](mailto: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



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](mailto:DICE@fda.hhs.gov)) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,



Long H. Chen -S  
2018.10.11 15:42:40  
-04'00'

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



