

## **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 **1,000,000 units**Shipped to over **4,200 facilities** 



# Device Key with Embedded Intelligence

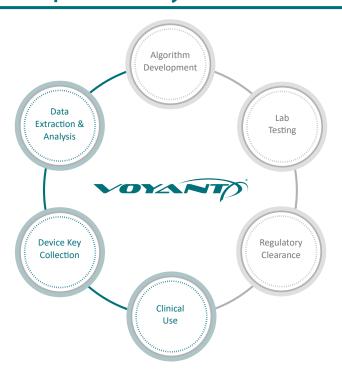
Optimizes energy delivery for procedural needs.

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 faster seal times, less adherence, decreased lateral thermal spread, and reduced smoke plume. 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.

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### 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.

#### **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°

**Blade Lever** 

Transects tissue with

a mechanical blade.

## 5mm Fusion Device

### **Unrestricted Shaft Rotation**

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



### **Blade Lever**

Transects tissue with a mechanical blade.



**Fuse Activation Button** 

Activates energy delivery.

# Single-Action, Straight Jaw with Blunt Tips

Enables a high degree of control during blunt tissue dissection.

# Spring-Loaded Handle Lever with Latch

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

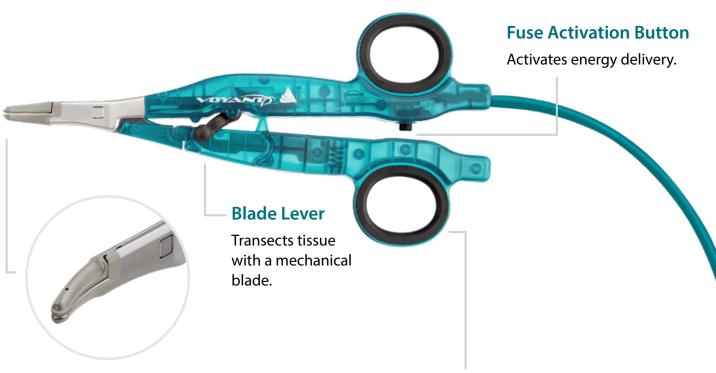
Opens automatically when unlatched.

### **Voyant 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

## Fine Fusion Device



# 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.

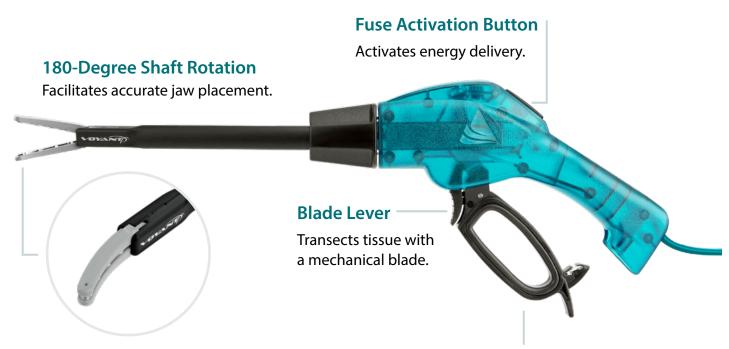
### **Ring Handle Insert**

Can be left in or removed to accommodate all hand sizes.

### **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

## **Open Fusion Device**



# **Dual-Action, Curved Jaw** with Blunt Tips

Aids in visualizing the tips of the jaw during tissue handling.

# 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 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	40mm	38mm	Curved, with blunt tips	180°

## Voyant

## **Electrosurgical Generator and Cart**

#### **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!



### **Voyant Electrosurgical Generator and Cart**

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

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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 <a href="https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm">https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm</a> 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 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 <a href="https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products">https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products</a>); 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 <a href="https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems">https://www.fda.gov/medical-device-problems</a>.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (<a href="https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance">https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance</a>) and CDRH Learn (<a href="https://www.fda.gov/training-and-continuing-education/cdrh-learn">https://www.fda.gov/training-and-continuing-education/cdrh-learn</a>). 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 (<a href="https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice">https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice">https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice</a>) for more information or contact DICE by email (<a href="DICE@fda.hhs.gov">DICE@fda.hhs.gov</a>) 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



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 <a href="https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm">https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm</a> 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

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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 <a href="https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products">https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products</a>); 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 <a href="https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems">https://www.fda.gov/medical-device-problems</a>.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (<a href="https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance">https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance</a>) and CDRH Learn (<a href="https://www.fda.gov/training-and-continuing-education/cdrh-learn">https://www.fda.gov/training-and-continuing-education/cdrh-learn</a>). 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 (<a href="https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice">https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice">https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice</a>) for more information or contact DICE by email (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



June 5, 2020

Applied Medical Resources Corp. Sherif Nakhla Regulatory Affairs Specialist 22872 Avenida Empresa Rancho Santa Margarita, California 92688

Re: K201212

Trade/Device Name: Voyant Open 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: May 5, 2020 Received: May 5, 2020

#### Dear Sherif Nakhla:

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 <a href="https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm">https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm</a> 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.

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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

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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 <a href="https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products">https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products</a>); 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 <a href="https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems">https://www.fda.gov/medical-device-problems</a>.

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Sincerely,

Long H. Chen -S Digitally signed by Long H. Chen -S Date: 2020.06.05 13:58:16 -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



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 <a href="https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm">https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm</a> 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.

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U.S. Food & Drug Administration 10903 New Hampshire Avenue Silver Spring, MD 20993 www.fda.gov K200598 - Blake Stacy Page 2

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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 <a href="https://www.fda.gov/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems">https://www.fda.gov/medical-device-problems</a>.

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Sincerely,

Long H. Chen -S Digitally signed by Long H. Chen -S 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



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 <a href="https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm">https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm</a> 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 <u>Federal Register</u>.

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 Page 2 – Mr. Andrew Nguyen

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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 <a href="https://www.fda.gov/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm">https://www.fda.gov/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm</a>); 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 <a href="http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm">http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm</a>.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (<a href="https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/">https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/</a>) and CDRH Learn (<a href="http://www.fda.gov/Training/CDRHLearn">http://www.fda.gov/Training/CDRHLearn</a>). 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 (<a href="http://www.fda.gov/DICE">http://www.fda.gov/DICE</a>) for more information or contact DICE by email (<a href="DICE@fda.hhs.gov">DICE@fda.hhs.gov</a>) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

FDA

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

### ABOUT APPLIED MEDICAL

Founded in 1987 and headquartered in Southern California, Applied Medical is a rapidly growing, global organization.

As a new generation medical device company, we are equally committed to improving both the affordability and the accessibility of high-quality healthcare. We are proud to have a significant and sustainable impact on healthcare by delivering technologies that enhance clinical care and satisfy the pressing economic needs of our customers.

Our dedicated Field Implementation team works with hospital administration teams, operating suite management and additional team members to plan a professionally implemented surgical device conversion and ensure a seamless transition to Applied Medical products. Applied Medical representatives are available on an ongoing basis for training and support of the hospital staff.

### **BUSINESS MODEL**

Applied Medical is guided by the belief that we are responsible for satisfying the three fundamental healthcare needs – cost containment, enhanced clinical outcomes and unrestricted choice. In light of this belief, we invest heavily in team members, R&D and advanced manufacturing technologies in order to develop the products and processes that allow us to satisfy our customers' needs.

One of the main facets of our business model is vertical integration. Instead of outsourcing our operations, we continuously focus on expanding our areas of expertise and manufacturing capabilities. As a vertically integrated organization, we manufacture our products in-house at our facilities in Southern California and Amersfoort, the Netherlands, and provide exceptional customer service, support and education.

Our high level of vertical integration allows us to quickly and efficiently make product enhancements and develop new technologies, reducing the amount of time required for innovative ideas to positively impact patient care. Vertical integration also allows us to control costs, closely manage supply lines, and ensure the highest product quality, availability and compliance.

#### Visit appliedmedical.com/voyant for more information.

Please contact your Applied Medical representative for more information on availability. This information is intended for dissemination exclusively to healthcare professionals and is not intended to replace labeling and Instructions for Use (IFU). Please refer to the IFU for the indications, contraindications, warnings, precautions, instructions and other information.



