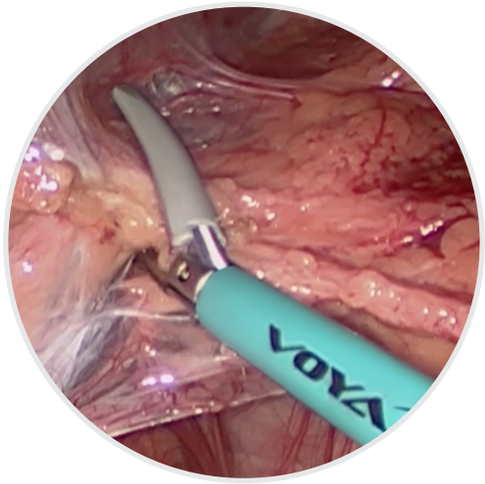
VOYANT®

INTELLIGENT ENERGY SYSTEM

Applied Medical

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 **60 countries**
Shipped over **820,000 units**
Shipped to over **4,100 facilities**

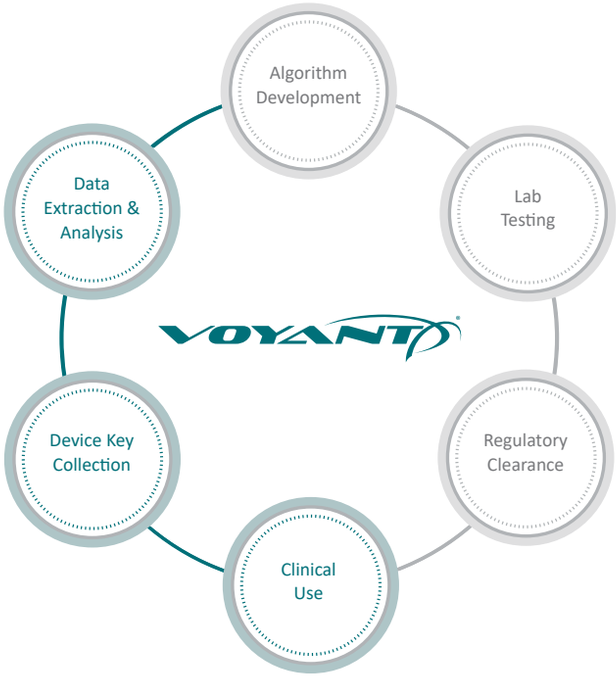
Device Key with Embedded Intelligence

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

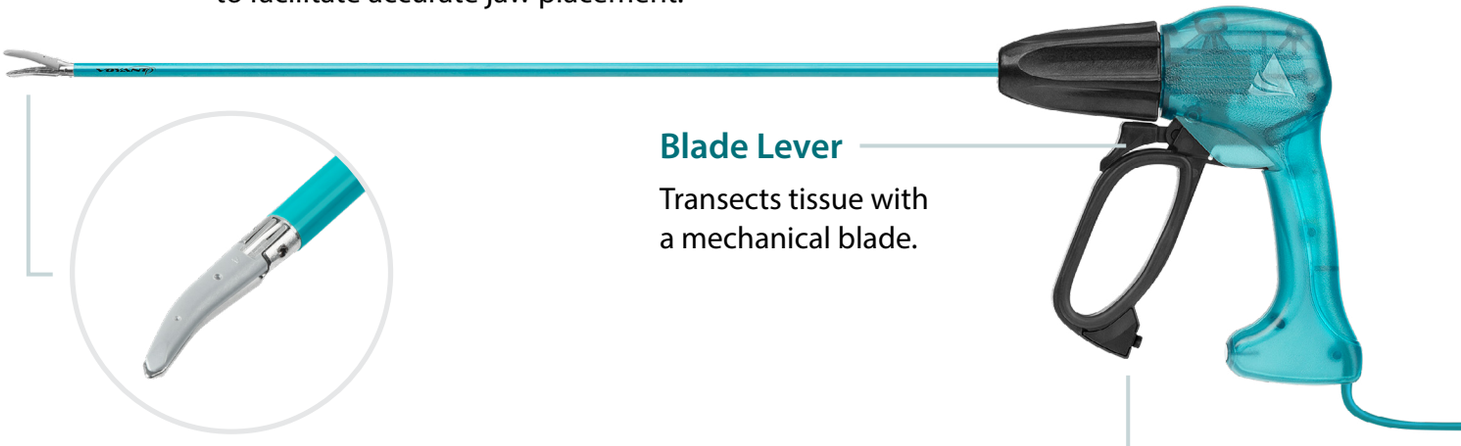
The Voyant system's continual energy optimization means Applied Medical can make each activation more efficient resulting in faster seal times, less adherence, decreased lateral thermal spread, and reduced smoke plume. The benefits of the Voyant system's efficient sealing can be easily recognized through 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.

Voyant

Maryland Fusion Device with Single-Step Activation

Unrestricted Shaft Rotation

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



Blade Lever

Transects tissue with a mechanical blade.

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.

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

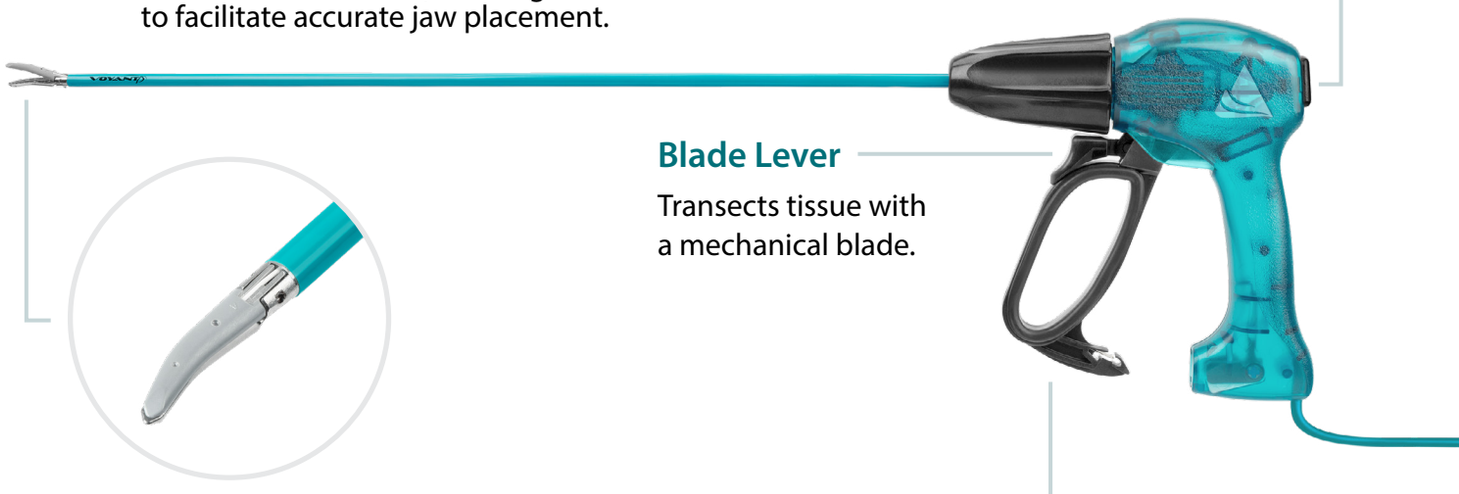
Maryland Fusion Device

Unrestricted Shaft Rotation

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

Fuse Activation Button

Activates energy delivery.



Blade Lever

Transects tissue with a mechanical blade.

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.

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

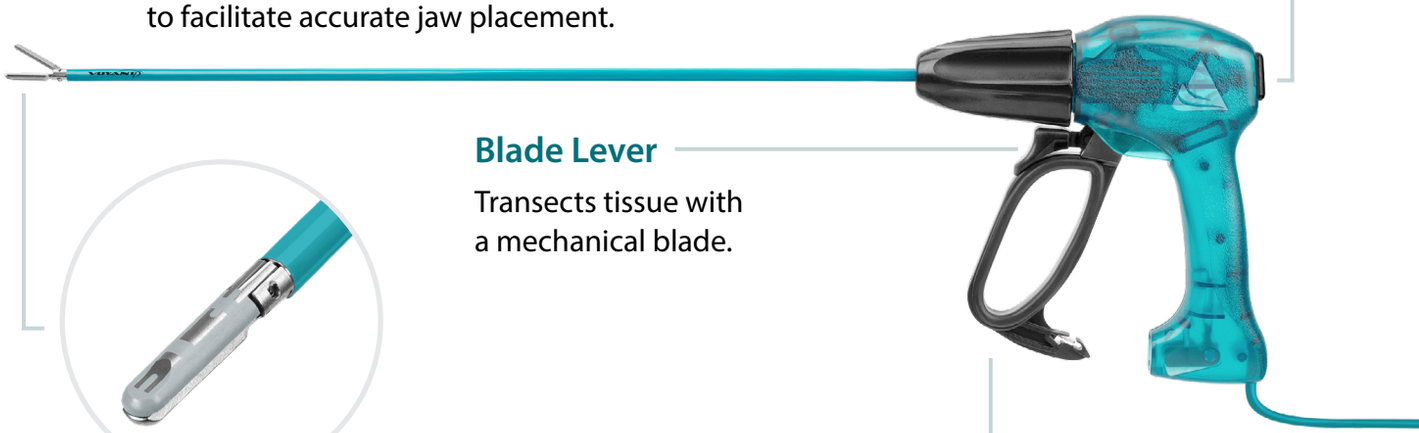
5mm Fusion Device

Unrestricted Shaft Rotation

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

Fuse Activation Button

Activates energy delivery.



Blade Lever

Transects tissue with a mechanical blade.

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.

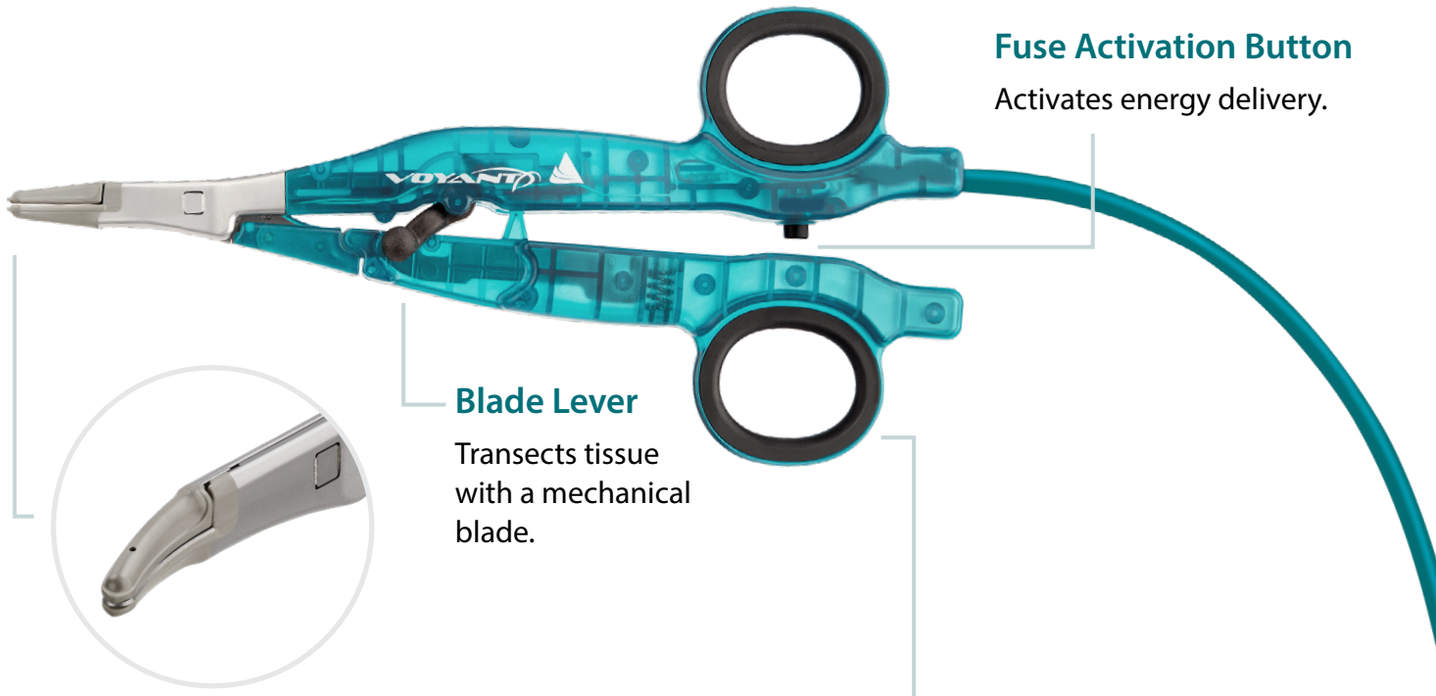
Opens automatically when unlatched.

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



Fuse Activation Button

Activates energy delivery.

Blade Lever

Transects tissue with a mechanical blade.

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.

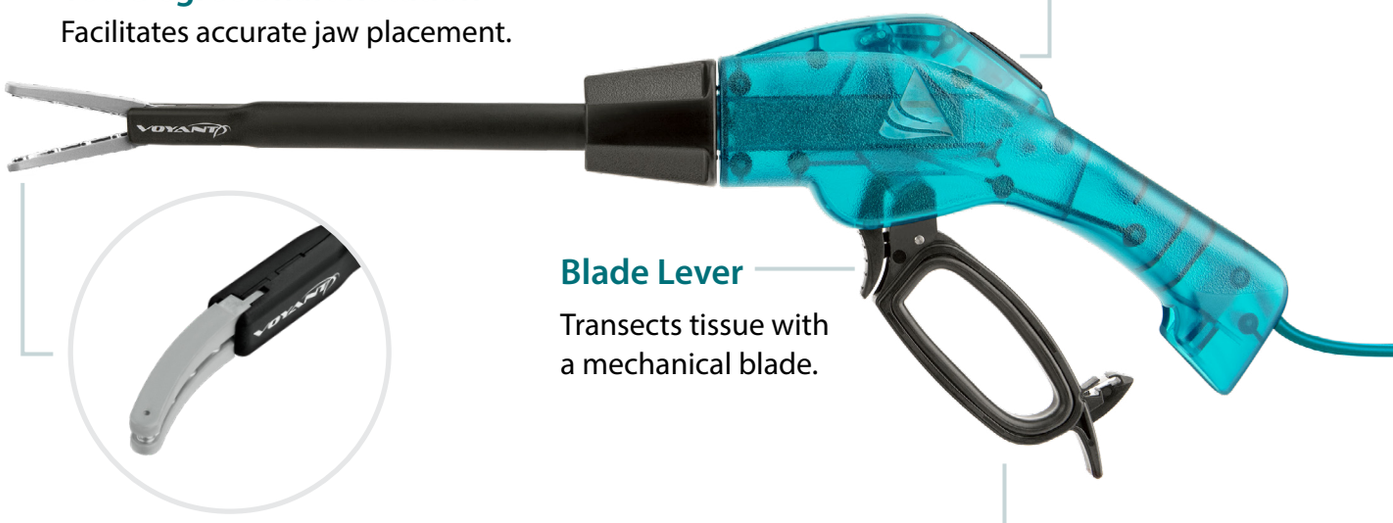
Voyant Fine Fusion Device

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

Voyant
Open Fusion Device

Fuse Activation Button
Activates energy delivery.

180-Degree Shaft Rotation
Facilitates accurate jaw placement.



Blade Lever
Transects tissue with a mechanical blade.

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 second-generation Voyant devices.

Seamless Script Software Updates

The Voyant Intelligent Energy system delivers the latest technology, embedded in each device key.

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

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

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,

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

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.

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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/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) 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

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.

U.S. Food & Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993
www.fda.gov

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 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

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.

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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 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.

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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

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 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

Note: The June 5, 2020 510(k) letter from the FDA includes the Voyant 5mm Fusion device.

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.

02/2023 405192-EN-A

Applied Medical