VOYANT®

INTELLIGENT ENERGY SYSTEM

Applied Medical

Voyant System
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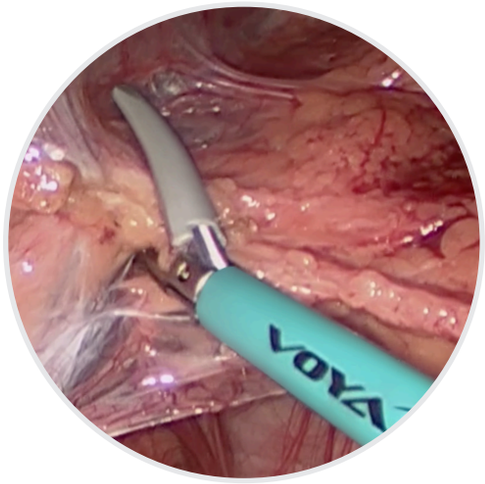
APPLIED MEDICAL BUSINESS MODEL 20

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 **50 countries**
Shipped over **540,000 units**
Shipped to over **3,100 facilities**

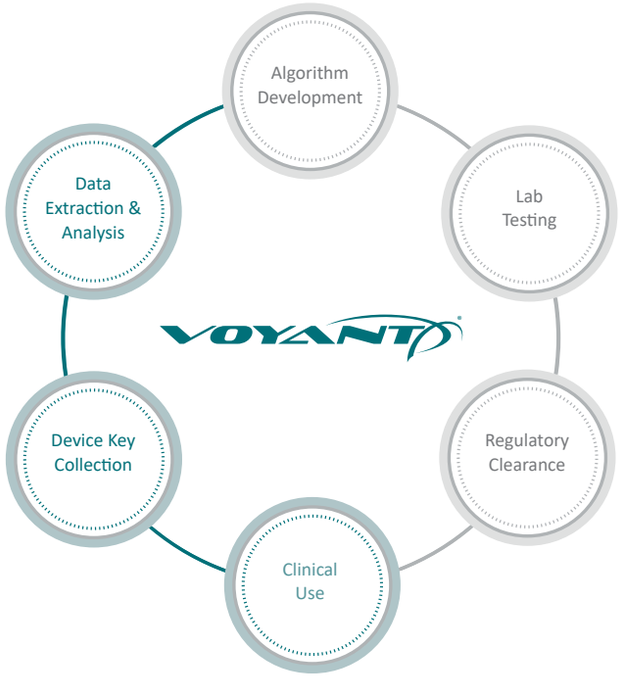
Device Key with Embedded Intelligence

Stores activation data to ***learn from live human tissue.***

Optimizes energy delivery for procedural and patient needs.

Enables efficient implementation of algorithm updates by delivering the most advanced technology with new handpieces.

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

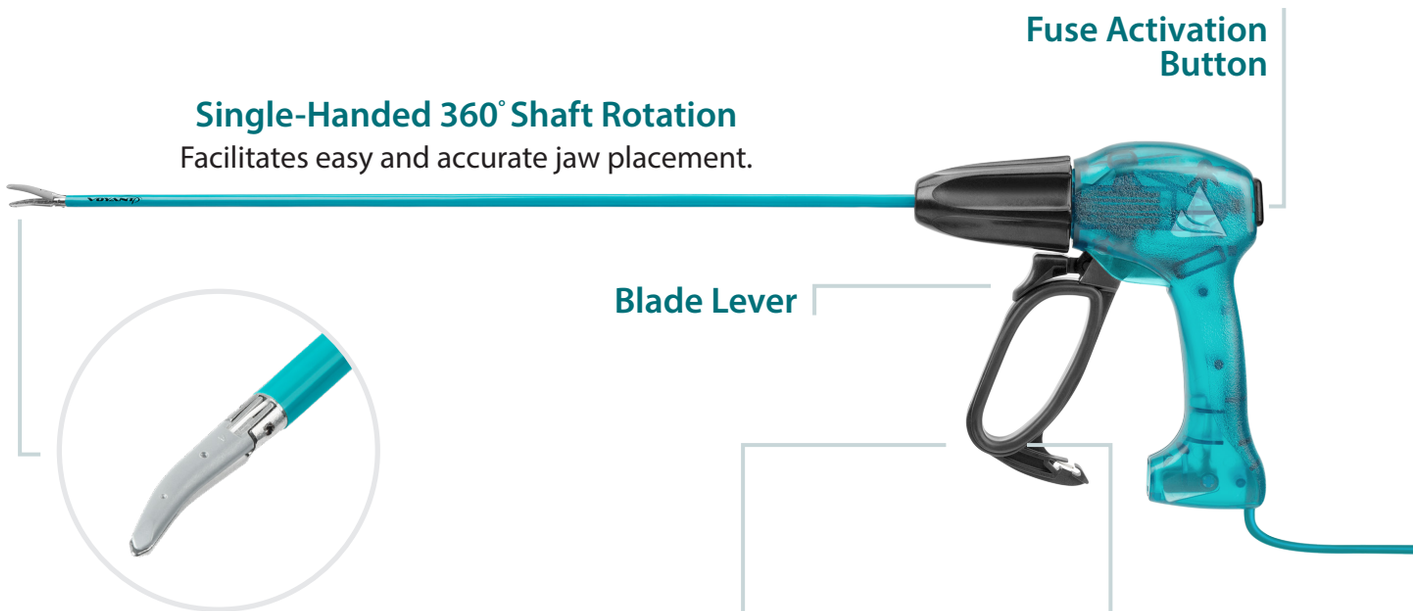
The Voyant device key connected to each handpiece stores activation data from each vessel or tissue bundle sealed throughout the procedure. By partnering with hospitals and surgeons to collect device keys, Applied Medical scientists and engineers are able to analyze the data to further optimize energy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



Single-Action, Curved Jaw with Dissecting Tip

Allows for optimal control during dissection, greater visualization of the jaws and tracking of the curvature of anatomical structures.

Provides enhanced tissue dissection.

Spring-Loaded Latching Handle

May result in less hand fatigue when activating and fewer inadvertent activations.

Handle Lever Insert

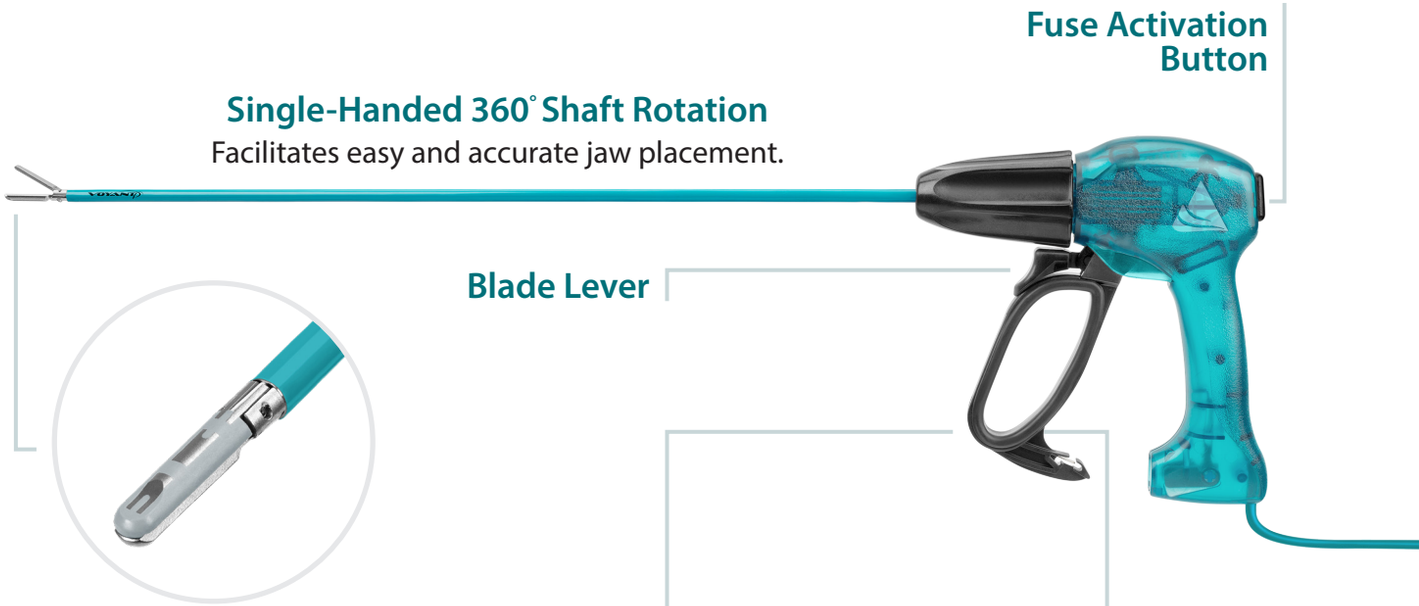
Accommodates various hand sizes.

Voyant Maryland Fusion Device

Model	Modality	Maximum Vessel Size	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 tip	360°
EB216	Advanced bipolar	7mm	44cm	Single action	Latching	5mm or larger	20mm	18mm	Curved with dissecting tip	360°
EB217	Advanced bipolar	7mm	23cm	Single action	Latching	5mm or larger	20mm	18mm	Curved with dissecting tip	360°

Voyant

5mm Fusion Device



Single-Action, Straight Jaw with Blunt Tip

Allows for optimal control during dissection.

Spring-Loaded Latching Handle

May result in less hand fatigue when activating the fuse button and opening the handle.

Handle Lever Insert

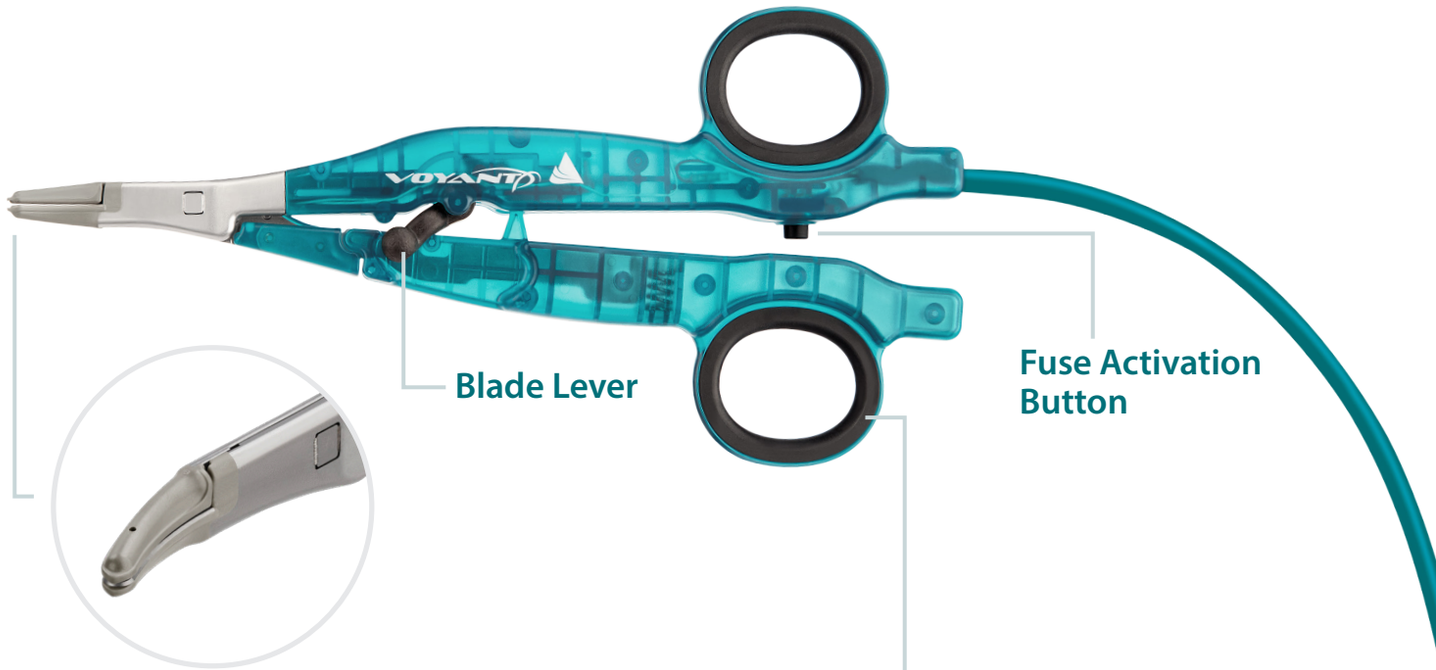
Accommodates various hand sizes.

Voyant 5mm Fusion Device

Model	Modality	Maximum Vessel Size	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 tip	360°
EB211	Advanced bipolar	7mm	44cm	Single action	Latching	5mm or larger	20mm	18mm	Straight with blunt tip	360°

Voyant

Fine Fusion Device



Dual-Action, Curved Jaw with Dissecting Tip

Allows for optimal control during dissection, greater visualization of the jaws and tracking of the curvature of anatomical structures.

Provides enhanced fine tissue dissection.

Ring Handle Insert

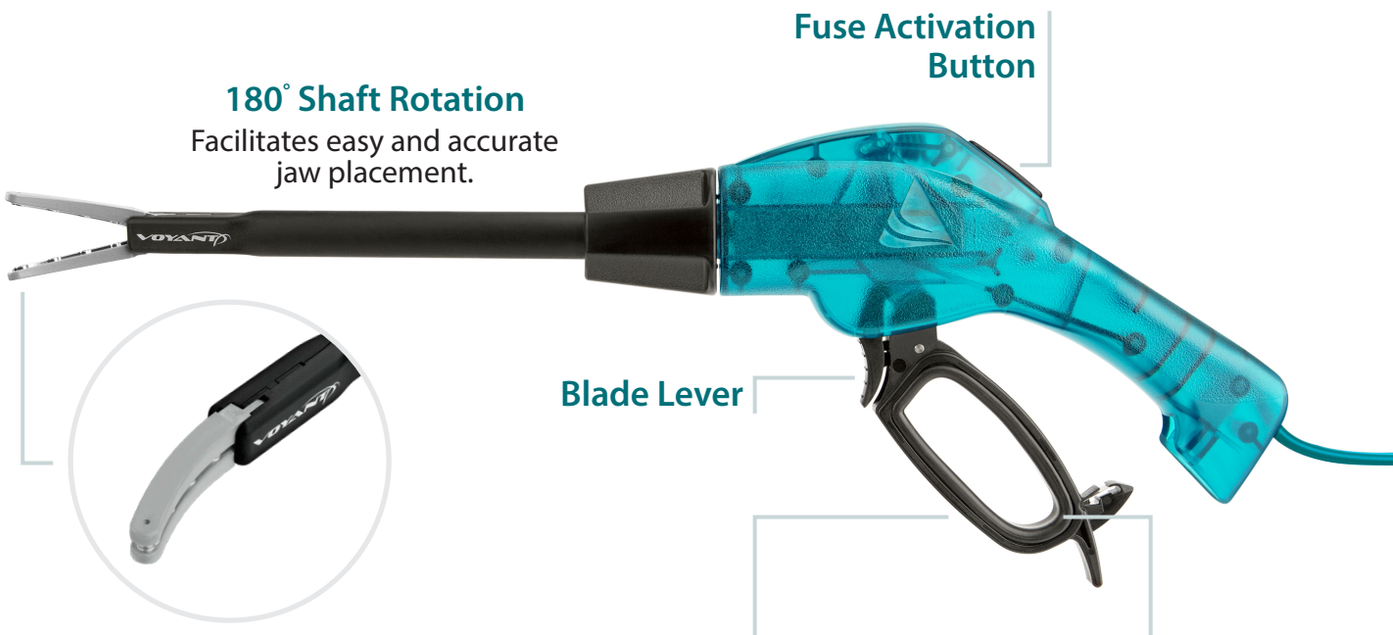
Accommodates various hand sizes.

Voyant Fine Fusion Device

Model	Modality	Maximum Vessel Size	Device Length	Jaw Style	Seal Length	Cut Length	Jaw Shape
EB230	Advanced bipolar	7mm, including head and neck	19.3cm	Dual action	17mm	15mm	Curved with dissecting tip

Voyant

Open Fusion Device



Dual-Action, Curved Jaw with Blunt Tip

Assists with visualization of the distal end of the jaws.

Spring-Loaded Latching Handle

Facilitates opening of the handle and jaws, minimizing the potential for hand fatigue.

Handle Lever Insert

Accommodates various hand sizes.

Voyant Open Fusion Device

Model	Modality	Maximum Vessel Size	Shaft Length	Jaw Style	Seal Length	Cut Length	Jaw Shape	Shaft Rotation
EB240	Advanced bipolar	7mm	20cm	Dual action	40mm	38mm	Curved with blunt tip	180°

Voyant

Electrosurgical Generator and Accessories

Advanced Energy
The EA020 Voyant generator is an advanced bipolar electrosurgical generator compatible with second-generation Voyant devices.

Seamless Software Updates
The Voyant Intelligent Energy system delivers the latest technology embedded in each device key.

Easy Preventive Maintenance
Output verification testing can be run at the touch of a button with the results displayed on-screen.

Sleek and Simple Design
The Voyant generator boasts a small profile and an easy-to-use user interface.

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

Voyant Electrosurgical Generator and Accessories

Model	Description	Modality	Product Size/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

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 established price of $_____ per handpiece. 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) EA020 Voyant electrosurgical generator(s) will be provided for use during the evaluation process. Any capital equipment provided by Applied Medical for use during the evaluation process remains the property of Applied Medical. The equipment shall not be removed from the facility and shall be returned upon Applied Medical's request. Customer shall bear the entire risk of damaged, lost or stolen equipment. 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, Customer will receive a 100% discount on the equipment. The discount does not take into account any current or future referrals or business. Customer must comply with all applicable laws concerning discounts, including anti-kickback laws, safe harbors, and associated reporting requirements. Customer should not seek reimbursement for any equipment from any federal or state program, but if reimbursement is sought it should be pursuant to a single reimbursement methodology.

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

CUSTOMER

_____
Signature

_____
Printed Name

_____
Title

_____
Email Address

_____
Date

APPLIED MEDICAL

_____
Signature

_____
Printed Name

_____
Title

_____
Date

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) 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

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

July 6, 2016

Applied Medical Resources
Ms. Jessica Cho
Manager, Regulatory Affairs
22872 Avenida Empresa
Rancho Santa Margarita, CA 92688

Re: K153017
Trade/Device Name: Voyant Fine Fusion
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical cutting and coagulation device and accessories
Regulatory Class: Class II
Product Code: GEI
Dated: May 31, 2016
Received: June 1, 2016

Dear Ms. Cho:

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. 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); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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 the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Jennifer R. Stevenson -A

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

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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Silver Spring, MD 20993
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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) 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

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, 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.

01/2022 141045-EN-USA-H