December 20, 2019

Erbe Elektromedizin GmbH
Julia Weller
Specialist Regulatory Affairs
Waldhoernlestrasse 17
Tuebingen, 72072 De

Re: K191234
Trade/Device Name: Erbe Argon Plasma Coagulation Unit APC 3 with Accessories
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical Cutting and Coagulation Device And Accessories
Regulatory Class: Class II
Product Code: GEI
Dated: May 3, 2019
Received: May 8, 2019

Dear Julia Weller:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's

requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Long Chen, Ph.D.
Assistant Director
DHT4A: Division of General Surgery Devices
OHT4: Office of Surgical
and Infection Control Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K191234

Device Name
Erbe Argon Plasma Coagulation Unit APC 3 with Accessories

Indications for Use *(Describe)*
The Erbe APC 3 with accessories is intended to deliver argon gas for argon plasma coagulation and ablation of tissue as well as argon-assisted cutting of tissue when used in conjunction with a compatible Erbe VIO Electrosurgical Generator (ESU) and applicators or probes.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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Erbe Elektromedizin GmbH
Traditional 510(k) for Erbe APC Unit Model APC 3 with Accessories

510(k) SUMMARY
[AS REQUIRED BY 21 CFR 807.92(C)]

Submitted By: Erbe Elektromedizin GmbH
Waldhoernlestrasse 17
72072 Tuebingen
Germany
Tel: 0049-7071-755-0
Fax: 0049-7071-755-179

Contact Person: Mr. Henry Kutz
Specialist Regulatory Affairs

Date Prepared: May 3, 2019

Trade/Proprietary Name: Erbe APC Unit Model APC 3 with Accessories

Common Name: Argon Plasma Coagulation Unit

Classification Name and Code: Electrosurgical Cutting and Coagulation Device and Accessories (21 CFR Part 878.4400)

Regulatory Class: II

Product Code: GEI

Legally Marketed Predicate Device: Erbe VIO APC Model APC 2 with Accessories, 510(k) Number K024047

Device Description:
The Erbe Argon Plasma Coagulation Unit Model APC 3 is an APC unit for use in conjunction with an Erbe Electrosurgical Unit (ESU) compatible Model (currently Model VIO® 3). The APC 3 (as well as VIO 3) can be mounted/secured to a cart or on a ceiling mount using fastening sets, i.e. connecting cables and hardware. The APC 3 is connected to an argon gas source via a pressure reducer and connected to the VIO 3 which powers and controls the APC unit. The ESU further provides a touch-screen monitor (i.e., interactive display) with an onscreen tutorial, settings and operational information as well as safety features (i.e., audio and visual error system). When using the APC 3 together with the VIO 3, the user is offered various APC Modes as well as argon-supported Modes which can be adjusted by the physician via effect levels in order to achieve the desired tissue effect. The ESU VIO 3 provides the high-frequency (HF) current required for thermal coagulation. For argon plasma coagulation and ablation, the HF current is applied non-contact to the tissue to be coagulated through ionized and hence electrically conductive argon gas (argon plasma). The argon gas is ionized in the high-frequency electrical field between the electrode of the applicator and the tissue. For argon-assisted cutting, the ESU provides the regular cutting/coagulation Mode while the argon gas provided by the APC 3 circulates the active electrode. This application is with contact to tissue.
Applicators or probes connected to the APC 3 for coagulating or ablating tissue via argon plasma and/or for cutting tissue supported by argon gas may be activated via footswitches connected to the ESU or by use of applicators that have an activation finger switch.

The APC unit and its accessories (i.e. pressure reducer and fastening sets) are supplied non-sterile and are reusable. Cleaning and disinfection instructions are provided in the APC

user manual or notes on use of the involved accessory. The compatible applicators and probes are provided sterile as well as are single-use.

Indications for Use Statement:
The Erbe APC 3 with accessories is intended to deliver argon gas for argon plasma coagulation and ablation of tissue as well as argon-assisted cutting of tissue when used in conjunction with a compatible Erbe VIO Electrosurgical Generator (ESU) and applicators or probes.

Similarities and Differences of the Modified Device to the Current Device (Predicate Comparison/Substantial Equivalence):

Characteristics	Predicate: Erbe VIO APC Model APC 2 with Accessories	Proposed: Erbe APC Unit Model APC 3 with Accessories
Manufacturer	Erbe Elektromedizin GmbH (Germany)	Same
510(k)	K024047	N/A
Trade/Proprietary Name	Erbe VIO APC Model APC 2 with Accessories	Erbe APC Unit Model APC 3 with Accessories
Indications for Use	The Erbe VIO APC with Accessories is intended to deliver argon gas for argon plasma coagulation of tissue when used in conjunction with a compatible Erbe VIO Electrosurgical Generator (ESU) and applicators or probes.	The Erbe APC 3 with accessories is intended to deliver argon gas for argon plasma coagulation and ablation of tissue as well as argon-assisted cutting of tissue when used in conjunction with a compatible Erbe VIO Electrosurgical Generator (ESU) and applicators or probes.
Prescription or OTC	Prescription (Rx)	Same
Materials		
Unit	Metal sheet, plastics, wiring, metal fittings	Same
Applicators	Stainless steel, ceramic, plastics, tungsten, printing color	Same
Probes	Stainless steel, ceramic, plastics, tungsten, glue, silicone	Same
Pressure Reducer	Metal, plastic, tubing, metal fittings, pressure gauge	Same
Fastening Sets	N/A	metal, wiring, plastics
Technical / Performance Data		
Unit gas flow rate (adjustable)	0.1-8 l/min limited by the respective instrument connected, adjustable in 0.1 l steps	Same
Gas Type Used	Argon 4.8 (99.998% purity) or higher	Same
Input/Line	No direct line input / powered through compatible VIO ESU	Same
Protective Circuits	Detection of specific type of accessory/instruments (e.g. applicator or probe) through the VIO ESU	Same

Erbe Elektromedizin GmbH
Traditional 510(k) for Erbe APC Unit Model APC 3 with Accessories

Characteristics	Predicate: Erbe VIO APC Model APC 2 with Accessories	Proposed: Erbe APC Unit Model APC 3 with Accessories
Receptacle Configuration	Up to two sockets. (one APC/FiAPC socket or two APC/FiAPC sockets or one APC/FiAPC socket and one monopolar/bipolar/ multifunctional socket)	Up to two sockets. (one FiAPC socket or one FiAPC socket and one monopolar/ bipolar/ multifunctional socket)
Units compatible with the APC Unit	Erbe ESU Model VIO D and VIO S series [K060484,K083452 and K080715]	Erbe ESU Model VIO 3 [K190823 - pending]
Applicators and Probes compatible with the APC Unit	APC raspatory handle and tip [K992764]	N/A
	APC applicator [K992769]	N/A
	APC handle and applicators [K003462]	N/A
	APCprobe [K013348]	N/A
	FiAPC probes [K060183]	Same
	HybridAPC probe [K143306]	Same
	APCapplicators [K183445]	Same
Other compatible equipment	VIO Cart [K023886]	Same
Labeling	APC 2 Unit - packaging label - user manual - service manual	APC 3 Unit - packaging label - user manual - service manual
	Applicators and probes - packaging label - notes on use	Applicators and probes - packaging label - notes on use Note: Compatibility to APC 3 added.
	Pressure reducer - packaging label - notes on use	Pressure reducer - packaging label - notes on use Note: Compatibility to APC 3 added.
	N/A	Fastening sets - packaging label
	VIO Cart - packaging label - user manual	VIO Cart - packaging label - user manual Note: Compatibility to APC 3 added.
Biocompatibility	APC Unit: N/A - no patient contact	Same
	Applicators and probes: direct patient contact	Same
	Pressure reducer and VIO Cart: N/A - no patient contact	Pressure reducer, VIO Cart and fastening sets: N/A - no patient contact
Provided condition	APC Unit : non-sterile, reusable	Same
	Applicators and probes: sterile, disposable (single-use)	Same
	Pressure reducer and VIO Cart: non-sterile, reusable	Pressure reducer, VIO Cart and fastening sets: non-sterile, reusable
Shelf Life	Not Applicable for reusable Unit and Accessories (i.e. pressure reducer and VIO Cart)	Not Applicable for reusable Unit and Accessories (i.e. pressure reducer, VIO Cart and fastening set)

Erbe Elektromedizin GmbH
Traditional 510(k) for Erbe APC Unit Model APC 3 with Accessories

Characteristics	Predicate: Erbe VIO APC Model APC 2 with Accessories	Proposed: Erbe APC Unit Model APC 3 with Accessories
	Three (3) years for single use HybridAPC probe and APCapplicators and five (5) years for FiAPC probes.	Same

Verification/Validation Activities (Including Applied/Certified Standards and Guidance Documents):

FDA Recognized Consensus Standards

- ANSI AAMI ES60601-1:2005/(R)2012 and A1:2012, C1:2009/(R)2012 and A2:2010/(R)2012 (Consolidated Text) Medical electrical equipment - Part 1: General requirements for basic safety and essential performance*
  *Other versions of this standard were also tested to and certified.
- IEC 60601-1-2 Edition 4.0:2014-02 Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests*
  *Other versions of this standard were also tested to and certified.
- IEC 60601-2-2 Edition 6.0 2017-03 Medical electrical equipment - Part 2-2: Particular requirements for the basic safety and essential performance of high frequency surgical equipment and high frequency surgical accessories*
  *Other versions of this standard were also tested to and certified
- IEC 62304:2006 + A1:2015 Medical device software - Software life cycle processes
- IEC 62366:2007 + A1:2014 Medical Devices - Application Of Usability Engineering To Medical Devices
- IEC 60601-1-6:2010 (Third Edition) + A1:2013 Medical electrical equipment - Part 1 - 6: General requirements for basic safety and essential performance - Collateral standard: Usability
- ISO 15223-1:2016 Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied - Part 1: General requirements
- EN 1041:2008 + A1:2013 Information supplied by the manufacturer of medical devices
- ISTA 2A:2011 Partial Simulation Performance Test - Packaged-Products 150 lb (68 kg) or Less

Performance Evaluations/Testing

- Output/Mode Comparison
- Tissue Testing
- Capacitive Coupling (per Standard Number 60601-2-2)
- Accessory Testing

Conclusion:

The intended use of the proposed Erbe APC 3 was clarified identifying all functions that may be performed with the Unit when used in combination with a compatible Erbe VIO ESU and applicators or probes. The proposed Unit has essentially the same principles of operation, technological characteristics, as well as performance characteristics as the predicate APC unit. Validation and verification activities in design control that includes testing/certification to designated standards (including electrical safety standards) and performance testing of the proposed devices has demonstrated substantial equivalence to the predicate.