April 4, 2019

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

Re: K183445
Trade/Device Name: Erbe APCapplicators
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical Cutting and Coagulation Device and Accessories
Regulatory Class: Class II
Product Code: GEI
Dated: January 2, 2019
Received: January 7, 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/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,

Jennifer R. Stevenson -S3

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

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)*
K183445

Device Name
Rigid Argon Plasma Coagulation Applicator (APCapplicator)

Indications for Use *(Describe)*
Product Number (P/N) 20132-250, 20132-251, 20132-252, 20132-253, 20132-254 and 20132-255: The Rigid Argon Plasma Coagulation Applicators are intended for monopolar cutting and coagulation of tissue with and without argon gas or for coagulation and ablation using argon plasma. They are used in open and in laparoscopic surgery.

P/N 20132-256: The Rigid Argon Plasma Coagulation Applicator is intended for monopolar coagulation and ablation of tissue using argon plasma. It is used in open surgical procedures.

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's APCapplicators

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

Submitted By: Erbe Elektromedizin GmbH
Waldhoernlestrasse 17
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Tel: 0049-7071-755-0
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Contact Person: Ms. Julia Weller
Specialist Regulatory Affairs

Date Prepared: December 7th, 2018

Trade/Proprietary Name: Erbe APCapplicators

Common Name: Rigid Argon Plasma Coagulation Applicators

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 APC Handle and Applicators – K003462

Device Description:
The Erbe APCapplicators are sterile, single-use electrosurgical instruments for monopolar cutting and coagulation with and without argon gas and/or for coagulation and ablation of tissue using argon plasma. They are used in open and/or laparoscopic surgical procedures. The APCapplicators are intended for use with an Erbe Argon Plasma Coagulator Unit Model APC 2 in combination with a compatible Erbe VIO® electrosurgical unit. Note that the APC 2 must be equipped with an APC receptacle with finger switch activation. Activation may either be done via finger switch on the handle of the Erbe APCapplicator or via footswitch.
The applicators are provided in various shaft lengths either with an adjustable spatula/needle electrode or a malleable tip. Adjustable means that by using the rotary wheel the spatula/needle electrode may either be fully withdrawn inside the instrument shaft or extended up to 14mm outside of the shaft. With an extended electrode the user may cut and coagulate tissue with or without argon gas.

Indications for Use:
Part Number (P/N) 20132-250, 20132-251, 20132-252, 20132-253, 20132-254 and 20132-255: The Rigid Argon Plasma Coagulation Applicators are intended for monopolar cutting and coagulation of tissue with and without argon gas or for coagulation and ablation using argon plasma. They are used in open and laparoscopic surgery.
P/N 20132-256: The Rigid Argon Plasma Coagulation Applicator is intended for monopolar coagulation and ablation of tissue using argon plasma. It is used in open surgical procedures.

Erbe Elektromedizin GmbH
Traditional 510(k) for Erbe's APCapplicators

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

Characteristics	Predicate: Erbe APC Handle and Applicators	Proposed: Erbe APCapplicators
Manufacturer	Erbe Elektromedizin GmbH (Germany)	Erbe Elektromedizin GmbH (Germany)
Submitter	Erbe USA Inc. (USA)	Erbe Erbe Elektromedizin GmbH
510(k) Number	K003462	N/A
Trade/ Proprietary Name	Erbe APC Handle and Applicators	Erbe APCapplicators
Indications for Use Statement	APC coagulation	Part Number (P/N): 20132-250, 20132-251, 20132-252, 20132-253, 20132-254 and 20132-255: The Rigid Argon Plasma Coagulation Applicators are intended for monopolar cutting and coagulation of tissue with and without argon gas or for coagulation and ablation using argon plasma. They are used in open and in laparoscopic surgery. P/N 20132-256: The Rigid Argon Plasma Coagulation Applicator is intended for monopolar coagulation and ablation of tissue using argon plasma. It is used in open surgical procedures.
Prescription or OTC	Prescription	Prescription
Materials	Stainless steel, ceramic, plastics, adhesive. Additionally 20132-044 and -054 include tungsten. Additionally 20132-040 includes tungsten and silicone. APC handle consists of stainless steel, plastics and silicone.	Stainless steel, ceramic, plastics, printing color. Additionally 20132-251, -253, -255 and -256 include tungsten.
Dimensions	- shaft diameter: 2.3mm, 5mm and 6mm - shaft length: 25mm, 35mm, 50mm, 100mm and 320mm	- shaft diameter: 5mm - shaft length: 35mm, 100mm and 350mm
Configurations	- shaft: straight or angled - tip: adjustable needle or spatula electrode, malleable tip, rigid tip	- shaft: straight - tip: adjustable needle or spatula electrode, malleable tip
Compatibility	ICC/APC 300, VIO/APC 2	VIO/APC 2
Sterilization Method Used	Steam sterilization	Ethylene Oxide
Shelf Life	N/A	three (3) years
Condition provided	non-sterile, reusable	sterile, single-use

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 (IEC 60601-1:2005, MOD)*
  *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 60601-2-18: Edition 3.0 2009-08 Medical electrical equipment - Part 2-18: Particular requirements for the basic safety and essential performance of endoscopic equipment
- ISO 15223-1:2016 Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied - Part 1: General requirements
- ISO 11135:2014 Sterilization of health-care products - Ethylene oxide -- Requirements for the development, validation and routine control of a sterilization process for medical devices
- ISO 11737-1 Second edition 2006-04-01 Sterilization of medical devices - Microbiological methods - Part 1: Determination of a population of microorganisms on products [Including: Technical Corrigendum 1 (2007)]
- ISO 11607-1 First edition 2006-04-15 Packaging for terminally sterilized medical devices - Part 1: Requirements for materials, sterile barrier systems and packaging systems [Including: Amendment 1 (2014)]
- ISO 11607-2 First edition 2006-04-15 Packaging for terminally sterilized medical devices - Part 2: Validation requirements for forming, sealing and assembly processes [Including: Amendment 1 (2014)]
- ISO 10993-1 Fourth edition 2009-10-15 Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process [Including: Technical Corrigendum 1 (2010)]

Performance Evaluations/Testing

- Tissue Testing
- Performance Testing

U.S Regulations

- 21 CFR 820.30, Design Controls
- 21 CFR 801, Labeling

Guidance Documents

- Guidance for Industry and FDA Staff: Format for Traditional and Abbreviated 510(k)s
- Premarket Notification (510(k)) Submissions for Electrosurgical Devices for General Surgery Guidance for Industry and Food and Drug Administration Staff
- Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling Guidance for Industry and Food and Drug Administration Staff
- Submission and Review of Sterility Information in Premarket Notification (510(k)) Submission for Devices Labeled as Sterile Guidance for Industry and Food and Drug Administration Staff
- Use of International Standard ISO 10993-1, "Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process" Guidance for Industry and Food and Drug Administration Staff

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Conclusion:
The proposed intended use was modified for clarification identifying all functions (e.g. cut and coagulation) that may be performed with the instruments as compared to the predicate devices which specify only argon plasma coagulation in their indications for use statement and rely on the intended uses of the compatible Units for the other available functions. Hence, the intended use of the proposed and predicate APC applicators is equivalent.
The notable difference when comparing the predicate and proposed devices, involves the predicate devices being reusable and the proposed devices being single use. Nevertheless, the functionality of both groups has been found to be the same.
The principles of operation and technological characteristics as well as the performance characteristics of the proposed and predicate device are equivalent. The materials used for the construction of the applicators are similar. Validation and verification activities in design control that include testing/certification to designated standards and performance testing of the proposed devices has demonstrated substantial equivalence to the predicate device. In conclusion, the proposed APCapplicators are as safe and efficacious as the predicate APC applicators.