May 22, 2019

Erbe Elektromedizin GmbH
% Mr. Mark Job
Regulatory Technology Services, LLC
1000 Westgate Drive,
Suite 510k
Saint Paul, Minnesota 55114

Re: K190823
Trade/Device Name: Erbe ESU Model VIO 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 10, 2019
Received: May 9, 2019

Dear Mr. Job:

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) 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,

for

Jennifer R. Stevenson
Acting Division 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)*
K190823

Device Name
Erbe's ESU Model VIO® 3 with Accessories

Indications for Use *(Describe)*
The Erbe Electrosurgical Unit (ESU/Generator) Model VIO® 3 with Accessories is intended to deliver High Frequency (HF) electrical current for the cutting and/or coagulation of tissue.

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 ESU Model VIO® 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
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Contact Person: Ms. Julia Weller
Specialist Regulatory Affairs

Date Prepared: February 13, 2019

Trade/Proprietary Name: Erbe ESU Model VIO® 3 with Accessories

Common Name: Electrosurgical Unit

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

Product Code: GEI

Legally Marketed Predicate Device: Erbe ESU Model VIO® 300 D with Accessories, 510(k) Number K083452

Device Description:

The Erbe ESU Model VIO® 3 with Accessories is an electrosurgical unit for the delivery of high frequency (HF) electrical current to cut and/or coagulate tissue via various universal instruments (e.g., electrodes, etc.).

ESU Model VIO 3
The ESU is a standalone Unit that can be mounted/secured to a cart or on a ceiling mount (Note: An A/C power cord is provided with the device.). It can integrate a compatible Erbe argon plasma coagulator as well as be used in conjunction with other equipment. The Generator has a touch-screen monitor (i.e., an interactive display) that provides the user with an onscreen tutorial as well as settings and operational information. The ESU has automatic start and stop features. Also, when activated, the device has an audio and visual error system (i.e., malfunctions or user errors are detected with medical personnel being alerted visually and/or by sound with, in some cases, no energy being delivered). The Unit has clearly defined cutting and coagulation modes based on various electrical waveforms and electrical parameters. Thermal effects on tissue can be different depending on the voltage, current, and the contact between electrode and tissue. With the available modes, the ESU provides physicians the flexibility in interventional applications. Finally, each mode has effect levels which can be finely adjusted by the physician in order to achieve the desired tissue effect.

Note: VIO stands for Variable Cut and Coagulation.

Erbe Elektromedizin GmbH
Traditional 510(k) for Erbe's ESU Model VIO® 3 with Accessories

Accessories

Footswitches

Various types of single and double pedal Footswitches have been designed for the ESU Model VIO 3. Specifically, the Footswitches are used to activate the Generator. Some of the Footswitches have a ReMode button so that the physician can toggle between preset programs. Also, some Footswitches are equipped with a divider and/or bracket (i.e., a bar) so that the operator can, as desired, have better foot control.

Connecting Cables

Monopolar and Bipolar Cables are standard in the industry. They provide HF output from the Generator to associated instruments.

Fastening Sets

The Sets include connecting cables and hardware to attach the ESU to a Cart or Ceiling Mount.

VIO Cart

The Cart provides mobility for the ESU and associated Accessories.

Indications for Use:

The Erbe Electrosurgical Unit (ESU/Generator) Model VIO® 3 with Accessories is intended to deliver High Frequency (HF) electrical current for the cutting and/or coagulation of tissue.

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

Characteristics	Current Predicate: Erbe ESU Model VIO 300 D with Accessories	Proposed: Erbe ESU Model VIO 3 with Accessories	Discussion
Manufacturer	Erbe Elektromedizin GmbH (Germany)	Erbe Elektromedizin GmbH (Germany)	Same
510(k) Number	K083452	N/A	N/A
Trade/ Proprietary Name	ERBE ESU Model VIO® 300 D with Accessories	Erbe ESU Model VIO® 3 with Accessories	New name
Indications for Use	The ERBE ESU Model VIO 300 D with Accessories is intended to deliver High Frequency (HF) electrical current for the cutting and/or coagulation of tissue.	The Erbe Electrosurgical Unit (ESU/Generator) Model VIO® 3 with Accessories is intended to deliver High Frequency (HF) electrical current for the cutting and/or coagulation of tissue.	Same
Prescription or OTC	Prescription	Prescription	Same
Frequency	350 kHz	350 kHz	Same
Maximum Output Power	370 Watts	400 Watts	Slightly greater maximum output power possible.
WiFi Feature	N/A	Available (deactivated by default, for service purposes only)	New feature.

Erbe Elektromedizin GmbH
Traditional 510(k) for Erbe's ESU Model VIO® 3 with Accessories

Characteristics	Current Predicate: Erbe ESU Model VIO 300 D with Accessories	Proposed: Erbe ESU Model VIO 3 with Accessories	Discussion
Output Modules / Receptacles	• monopolar receptacle • bipolar receptacles • receptacle for neutral electrodes	• monopolar receptacle • bipolar receptacles • universal receptacle • receptacle for neutral electrodes	Additional type of receptacle (universal receptacle).
Modes	• Monopolar Cutting and Coagulation Modes • Bipolar Cutting and Coagulation Modes If connected to a compatible Argon Plasma Coagulator: • APC Modes • argon-assisted Cutting and Coagulation Modes	• Monopolar Cutting and Coagulation Modes • Bipolar Cutting and Coagulation Modes If connected to a compatible Argon Plasma Coagulator: • APC Modes • argon-assisted Cutting and Coagulation Modes	Same (Note: Amount of Modes available is less in the proposed Unit than in the predicate ESU)
Mode Adjustment	Select voltage and set power limitation	Select effect (comprises defined power output and voltage limitation)	Different.
User Interface Screen	LED display and selection buttons	Touchscreen display	Different type of display. Both displays provide the user with an onscreen tutorials as well as relevant information.
Active Accessories - Cables	• return electrode connecting cable • monopolar connecting cables	• return electrode connecting cable • monopolar connecting cables • bipolar connecting cables	Additional type of cable (bipolar connecting cables).
Miscellaneous Accessories - Footswitches and Cart	• one- and two-pedal footswitches (only compatible with ESU Model VIO 300 D) • Cart	• one- and two-pedal footswitches (only compatible with ESU Model VIO 3) • Cart	Proposed footswitches are only compatible with VIO 3. New footswitch types added.
Materials	**Unit** Metal sheet, glass display screen, plastics, wiring **Accessories** Insulation plastics, wiring, metals, aluminum, rubber, metal sheet	**Unit** Metal sheet, glass display screen, plastics, wiring **Accessories** Insulation plastics, wiring, metals, aluminum, rubber, metal sheet	Same
Condition provided / Use condition	• Non-sterile / reusable (ESU and Footswitches) • Sterile / reusable (Cables)	• Non-sterile / reusable (ESU and Footswitches) • Sterile / reusable (Cables)	Same

Verification/Validation Activities (Including Applied/Certified 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 60601-1-2 Edition 4.0 2014-02 Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests*
  *Other versions of this standard were also tested to and certified.
- ANSI AAMI IEC 60601-2-2:2009 Medical electrical equipment - Part 2-2: Particular requirements for the basic safety and essential performance of high frequency surgery equipment and high frequency surgical accessories*
  *Other versions of this standard were also tested to and certified.
- IEC 60529:2013 Degrees of Protection Provided by Enclosures (IP Code)
- AAMI ANSI IEC 62304:2006 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
- IEC 17664:2004 Sterilization of medical devices - Information to be provided by the manufacturer for the processing of resterilizable medical devices
- ANSI AAMI ST81:2004 Sterilization of medical devices – Information to be provided by the manufacturer for the processing of resterilizable medical devices (only for cables)
- ISO 10993-1:2009 Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process (only for cables)
- ISTA 2A:2011 Partial Simulation Performance Test - Packaged-Products 150lb (68kg) or Less

Performance Evaluations/Testing

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

Conclusion:

The Erbe ESU Model VIO 3 with Accessories has the same intended use as well as essentially the same principles of operation and technological characteristics as the predicate devices in the previously cleared 510(k)s. 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 Erbe ESU Model VIO 300 D with Accessories (i.e., the predicate devices).