DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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May 5, 2016

ERBE Elektromedizin GmbH
Mr. Axel Retzlaff
Director of Regulatory Affairs
Waldhoernlestr. 17
Tuebingen, Germany 72072

Re: K150364
Trade/Device Name: ERBE ESU Model VIO dV with Accessories
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical cutting and coagulation device
Regulatory Class: Class II
Product Code: GEI
Dated: May 2, 2016
Received: May 4, 2016

Dear Mr. Retzlaff:

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 Industry and Consumer Education 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" (21CFR 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 Industry and Consumer Education 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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K150364

Device Name
ERBE ESU Model VIO dV with Accessories

Indications for Use *(Describe)*
The ERBE ESU Model VIO dV with Accessories is intended to deliver High Frequency (HF) 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 ESU Model VIO dV with Accessories

510(k) SUMMARY

As Required by 21 CFR 807.92(c)

Owner/Operator:	ERBE Elektromedizin GmbH Waldhoernlestr. 17 72072 Tuebingen Germany Phone +49-7071-755-0 Fax +49-7071-755-179 Contact: Axel Retzlaff, Director RA
Date Prepared:	20/01/2015
Trade (Proprietary) Name:	ERBE ESU Model VIO dV with Accessories
Common Name:	Electrosurgical Unit (ESU/Generator) System
Classification Name:	Electrosurgical Cutting and Coagulation Device and Accessories (21 CFR 878.4400)
Product Code:	GEI
Legally Marketed Predicate Device:	ERBE ESU Model VIO dV with Accessories, 510(k) Number K133180 ERBE ESU Model 300 D with Accessories, 510(k) Number K083452

Description of the Device:

The ERBE ESU Model VIO dV with Accessories is an ElectroSurgical Unit that generates High Frequency (HF) electrical current to cut and/or coagulate tissue. The ESU has clearly defined Cutting and Coagulation Modes with different electrical waveforms and electrical parameters, which are programmed with defined Effect levels. The available Modes are Auto Cut, Dry Cut, Swift Coag, Forced Coag, and Bipolar Soft Coag with and without Auto Stop and BiClamp. Each Effect level corresponds to a specific voltage. The Modes provide the

physician flexibility in interventional applications. Thus the Unit may be used for a broad array of surgical applications.

The ESU user interface consists primarily of a touchscreen surrounded by a small number of physical controls, such as a power switch and connection points for the instruments and accessories with which the generator is compatible.

Various hand instruments and neutral electrodes from ERBE and different manufacturers may be attached to and operated by the generator. The standard Accessories for the ESU consist of reusable Footswitches as well as Monopolar and Bipolar Cables

The VIO dV has a RCB (Remote Communication Bus) for remote control operation by the da da Vinci Xi Surgical System by Intuitive Surgical Inc. To have the unit installed as part of the da Vinci Xi Surgical System, contact Intuitive Surgical

Intended Use:

The ERBE ESU Model VIO dV with Accessories is intended to deliver High Frequency (HF) current for the cutting and/or coagulation of tissue.

Summary of the Technological Characteristics:

Similarities between modified and predicate devices:

Unit:

The proposed device ERBE ESU Model VIO dV (remote) compares to the predicate device ERBE ESU Model VIO dV (standalone) as follows:

Both devices have the same intended use, the same basic technology, protective circuits, and use the same basic accessories. Both devices are identical in hardware design including all materials and are using the same energy source. Both generators have the same user interface displays to select modes, power settings, etc. and both have the same Modes Auto Cut, Dry Cut, Swift Coag, Forced Coag, Bipolar Soft Coag with and without AutoStop function. Also, both units have audio and visual error monitoring.

ERBE ESU Model VIO dV with Accessories

The subject ESU and the predicate devices are manufactured by ERBE Elektromedizin GmbH in Germany and are supplied as non-sterile and are reusable. The packaging is also the same for both devices with similar labeling (e.g. Outer Package Label, User Manual, etc.). The proposed device ERBE ESU Model VIO dV (remote) compares to the predicate device ERBE ESU Model VIO 300 D as follows:

Both devices have the same BiClamp Mode.

Accessories:

The one pedal and two pedal footswitches are the same for both the subject and the predicate devices. The packaging is also the same with equal labeling.

Differences between modified and predicate devices:

The proposed device ERBE ESU Model VIO dV (remote) differs from the predicate device ERBE ESU Model VIO dV (standalone) as follows:

The proposed device has an updated Software Version 3.1 (predicate: 3.0) as the device is intended for remote control including HF-activation and change of settings via Intuitive Surgical, Inc.'s Da Vinci Surgical System. The BiClamp Mode which was disabled in the predicate ERBE ESU Model VIO dV is enabled in the proposed device. The User Manual was modified to appropriately address both changes.

Performance Data to determine Substantial Equivalence

The release of the software version 3.1 for the RCB remote control of the ERBE ESU Model VIO dV has been verified and validated as part of the design control. Software validation for remote control functions has been carried out for the VIO dV Software 3.1 as well as for the integrated system (VIO dV and da Vinci system). Testing/measurement of the output parameters of the BiClamp-Mode was carried out to show that the ESU's BiClamp-Mode performs as specified and in accordance with the specifications of the predicate device ERBE ESU Model VIO 300 D.

ERBE Elektromedizin GmbH, in accordance with established procedures, directs and controls design activities. These procedures involve design and development planning,

design input, design review, design verification/design output, design validation, design transfer, as well as design change control. The activities provide the oversight and forum for project approval, formal management/design review, evaluation, and final project approval. This work is documented within design review and the approvals are documented as part of the current change control system.

The ERBE ESU Model VIO dV, software version 3.1 for the RCB remote control complies to FDA's "Recognized Consensus Standards". Animal or clinical performance testing was not considered necessary.

Conclusion:

The software release version 3.1 and modification of the ERBE ESU Model VIO dV has the same intended use, principles of operation and technological characteristics as the predicate devices in the previously cleared 510(k)s. The subject device has been verified and validated in design control. There are no issues with the subject device that would raise additional safety or efficacy issues, when compared to the predicate devices.