ERBE USA Incorporated
Special 510(k) for ERBE ESU Model VIO dV with Accessories

October 2013

510(k) SUMMARY
[As Required by 21 CFR 807.92(c)]

Owner/Operator:	ERBE USA Incorporated 2225 Northwest Parkway Marietta, GA 30067
Trade (Proprietary) Name:	ERBE ESU Model VIO dV with Accessories
Common Name:	Electrosurgical Unit (ESU/Generator)
Classification Name, Number, and Product Code:	Electrosurgical, Cutting & Coagulation & Accessories; 21 CFR 878.4400; GEI
Legally Marketed Predicate Device:	ERBE ESU Model VIO 300 D with Accessories, 510(k) Number K083452 Note: VIO stands for Variable Cut and Coagulation.

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. It is a stand-alone generator. The ESU has five clearly defined Cutting and Coagulation Modes with different electrical waveforms and electrical parameters, which are programmed with defined Effect levels. 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

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 ERBE ESU Model VIO dV has the same intended use, the same basic technology, protective circuits, and uses the same basic accessories as the predicate ESU (ERBE Model VIO 300 D). Also, the Modes available in the ERBE ESU Model VIO dV ESU [i.e. Auto Cut, Dry Cut, Swift Coag, Forced Coag, and Bipolar Soft Coag with and without Auto Stop] are the same in the predicate. Both generators have user interface displays to select modes, power settings, etc. and have the AutoStop function. Also, both units have audio and visual error monitoring.

The subject ESU and the predicate device both 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.).

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 similar labeling.

Differences between modified and predicate devices:

The ERBE ESU Model VIO dV differs from the predicate ERBE ESU Model VIO 300 D as follows:

Subject device	Predicate device
- the unit has a square shape (408 x 163 x 380 mm) with rounded front panel	- the unit is of 'cake slice' shape (425 x 211 x 462 mm) with square front panel
- the ESU has a 10" Touchscreen color monitor display	- it has 6" button and LED color monitor display
- it has 4 HF receptacles in the front panel (2 monopolar and 2 bipolar) with instrument recognition on both the monopolar and bipolar receptacles.	- it has 3 HF receptacles in the front panel (monopolar, bipolar, multifunction)
- it has a receptacle for a CAN-bus for a remote controller	- it has no receptacle for a CAN-bus for a remote controller
- it has no receptacle for an APC unit	- it has a receptacle for an APC unit
- it has a firewall function	- it has no firewall function

- it has no programming capabilities - it ha a recall function - the modes that are present are the principal ones to perform essential cutting and coagulating activities. Auto Cut, Dry Cut, Swift Coag, Forced Coag., Soft Coag, Soft Coag with AutoStop, , No new modes are added.	- it has 99 program possibilities - it has no recall function - the predicate has a wide range of modes such as Auto Cut, High Cut, Dry Cut, Dry Cut °, Precise Cut, Soft Coag, Soft Coag with AutoStop, Swift Coag, Swift Coag °, Classic Coag, Forced Coag, Spray Coag, Precise Coag, Twin Coag, Bipolar Cut, Bipolar Cut +, Bipolar Precise Cut, Endo Cut Q, Endo Cut I, Bipolar Soft Coag +, Bipolar Forced Coag, BiClamp, Bipolar Precise Coag, Precise APC, Forced APC, Pulsed APC, Argon-assisted High Cut, Argon-assisted AUTO Cut, Argon-assisted Dry Cut, Argon-assisted Dry Cut °, Argon-assisted Swift Coag, Argon-assisted Swift Coag °, Argon-assisted Soft Coag, Argon-assisted Forced Coag and Argon-assisted Twin Coag (Note: Only some of these Modes are standard with the predicate device.).

The ERBE ESU Model VIO dV with Accessories has been verified or validated in design control.

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 with Accessories was tested to FDA's "Recognized Consensus Standards". Animal or clinical performance testing was not considered necessary.

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

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

ERBE USA Incorporated
Mr. John Tartal
Quality Assurance/Regulatory Affairs Director
2225 Northwest Parkway
Marietta, Georgia 30067

December 11, 2013

Re: K133180
Trade/Device Name: ERBE ESU Model VIO dV 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: November 11, 2013
Received: November 12, 2013

Dear Mr. Tartal:

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" (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 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,

Joshua C. Nipper -S

For Binita S. Ashar, M.D., M.B.A., F.A.C.S.
Acting Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K133180

Device Name: ERBE ESU Model VIO dV with Accessories

Indications For Use:

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

Prescription Use ___X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

DSD—Division Sign-Off

Division of Surgical Devices

510(k) Number: K133180

Long H. Chen -A

Digitally signed by Long H. Chen -A
DN: c=US, o=U.S. Government, ou=HHS, ou=FDA, ou=People, cn=Long H. Chen -A, 0.9.2342.19200300.100.1.1=13003690056
Date: 2013.12.10 08:26:51 -05'00'

for BSA