510(k) SUMMARY

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Submitted By:

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Contact Person: Julie Stephens, President/Consultant
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Date Prepared: November 20, 2008

Common Name: ElectroSurgical Unit (ESU/Generator) System

Trade/Proprietary Name: ERBE ESU Model VIO 300 D with Accessories

Classification Name: Electrosurgical cutting and coagulation device and accessories (21 CFR 878.4400)

Product Code: GEI

Legally Marketed Predicate Device: ERBE VIO ESU (Model VIO 300 D) with Accessories
510(k) Numbers: K023886 and K060484

Device Description:

The ERBE ESU Model VIO 300 D with Accessories is an electrosurgical system that uses High Frequency (HF) electrical current waveforms to cut and/or coagulate tissue. There are modifications made to only a few of the Accessories from the previously cleared 510(k) Number K023886 and they are included within this submission.

ESU Model VIO 300 D
The ESU has a color monitor display that provides the user with an on-screen tutorial as well as settings and operational information. The unit has various cutting and coagulation modes with defined effect levels to provide the physician flexibility in interventional applications (i.e. its ability to generate HF current). The system has automatic start and stop features. The equipment is programmable and various accessories (e.g. footswitches, hand instruments, etc.) as well as modes may be assigned to perform specific functions. 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). Upon activation, the energy delivered (in watts) from the ESU to the tissue is displayed on the display screen.

Also, the Unit can be used in association with an ERBE compatible Argon Plasma Coagulator (APC). The ESU is supplied non-sterile and is reusable.

Accessories (Modified VIO Footswitches)
Various types of single and double pedal Footswitches have been designed for ESU VIO Models. 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 bracket (i.e. bar) so that the operator can position their foot.

Note: VIO stands for Variable Cut and Coagulation.

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.

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

Similarities

ESU Model VIO 300 D
The modified ESU has the same intended use, protective circuits, and uses the same basic accessories (i.e. A/C Cord, Adapters, etc.) as the predicate. Also, the Modes with and without Auto Stop in the modified device are the same Modes that are in the predicate. Both Generators have an on-screen tutorial as well as the same user interface display to select modes, power settings, etc. The modified and predicate devices are programmable and have ReMode capabilities. Both devices have Auto Start and Auto Stop functions. Also, each Unit has audio and visual error monitoring. The modified and predicate devices both can be used with a compatible Argon Plasma Coagulator (APC) with the respective APC being controlled through the ESU. Both Units have the actual software for the APC within the ESU. The APC related Modes for the modified device are the same as the predicate device. The modified ESU is also manufactured by ERBE Elektromedizin GmbH in Germany and like the predicate Generator will be supplied as non-sterile and is reusable. The packaging is also the same for each device with similar labeling (e.g. Outer Package Label, User Manual, etc.).

Accessories (Modified VIO Footswitches)
The modified Footswitches are manufactured with the same type of materials and have the same functions as well as features as the predicate Footswitches. The packaging is also the same for each device with similar labeling (e.g. Outer Package Labels and Notes On Use, etc.).

Differences

ESU Model VIO 300 D
The modified ESU has the following changes or additions:
Hardware

- The method for installing an optional software mode utilizes a communications cable with a "serialized" dongle which requires changes to the internal communications Printed Circuit Boards (PCBs).
- Several internal PCBs are upgraded with more robust components to prevent field issues and errors.
- The display is more durable and the anti-reflective coating on the display screen is improved.
- The monopolar receptacle was improved to prevent the connection of instrument cables being inserted into the wrong holes of the module.
- An additional type of bipolar receptacle was created to further meet customer's needs.

Software

- Software changes are made to correct field issues and incorrect error situations.
- With some of the modes, the association of effects with power (outputs) and resistance were optimized and crest factors changed.
- Some visual cues and audio cues were improved (e.g. lighting of specific icons, change in tone or increased sound for a mode or feature, added power display for specific bipolar modes).
- The Endo Cut "I" and BiClamp modes have higher maximum output powers for the availability of more power if needed.
- The Auto Start and Auto Stop features are now available with additional modes.
- An additional feature was created for the Neutral Electrode Safety SYstem (NESSY) involving the use of a Neonatal Neutral Electrode (NE) (also referred to as Return Electrode, Patient Pad, Patient Plate, Grounding Pad, etc.). With the feature being turned "On", the Unit will display the message: "*NE Neonatal Monitoring - reduce the effect or power setting*" if a current of 300mA is reached.
- Upon connecting a recognized reusable instrument into the Unit, the following additional message displays: *"the instrument has already been sterilized around xx times"* to provide usage information.
- An additional method for toggling between preset programs (i.e. the ReMode feature) was added. That is, toggling between preset programs can be done by simultaneously pushing the Cut (Yellow) and Coag (Blue) buttons of a handswitch device.
- A "Maximum application time" setting is added to the Precise APC mode to reduce the possibility of thermal damage with the mode.
- Added identification field so that its identity can be displayed when the Unit is turned "On"

- The maximum voltage for High Cut and Argon-Assisted High Cut modes has been changed in the User Manual from being the average value to the maximum number with the tolerance added.

Accessories (Modified VIO Footswitches)
Footswitches with different configurations (i.e. single or double pedals, with or without ReMode, and with or without a bar) have been developed. Also, the Footswitches will be manufactured in house at ERBE Elektromedizin GmbH.

All of the modifications (i.e., additions and changes) for the ERBE ESU Model VIO 300 D with Accessories have been verified or validated in design control. All of the changes and additions as necessary are reflected in the labeling.

Conclusion:

The ERBE ESU Model VIO 300 D with Accessories has the same intended use, principles of operation, and technological characteristics as the predicate devices in the previously cleared 510(k)s. All of the modifications have been verified or validated in design control. In conclusion, there are no issues with the ERBE ESU Model VIO 300 D with Accessories 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
9200 Corporate Boulevard
Rockville MD 20850

DEC 31 2008

ERBE, USA Inc.
% Regulatory Resources Group Inc
Ms. Julie Stephens
111 Laurel Ridge Drive
Alpharetta, Georgia 30004

Re: K083452
Trade/Device Name: ERBE USA, Inc.'s ERBE ESU Model VIO 300 D with Accessories
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical cutting and coagulation device and accessories
Regulatory Class: II
Product Code: GEI
Dated: November 20, 2008
Received: December 1, 2008

Dear Ms. Stephens:

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.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such 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); 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.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. 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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K083452

Device Name: ERBE USA, Inc.'s ERBE ESU Model VIO 300 D with Accessories

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.

Prescription Use ___X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

David Krause for MKM

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K083452