K080715

APR - 2 2008

ERBE USA Incorporated **CONFIDENTIAL**
Special 510(k): ERBE ESU Model VIO 200 S

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510(k) SUMMARY

Submitted By:	ERBE USA, Inc. 2225 Northwest Parkway Marietta, GA 30067 Tel: 770-955-4400 Fax: 770-955-2577
Contact Person:	John Tartal QA/RA Manager
Date Prepared:	March 10, 2008
Common Name:	ElectroSurgical Unit (ESU/Generator)
Trade/Proprietary Name:	ERBE ESU Model VIO 200 S
Classification Name:	Electrosurgical cutting and coagulation device and accessories (21 CFR 878.4400)
Product Code:	79GEI
Legally Marketed Predicate Device:	ERBE VIO ESU (Model VIO 300 D), 510(k) Number: K060484

Device Description:

The ERBE ESU Model VIO 200 S is an ESU that uses High Frequency (HF) electrical current waveforms to cut and/or coagulate tissue. It has a display as well as various cutting and coagulation modes with defined effect levels to provide the physician flexibility in interventional applications (i.e. its ability to generate the 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 as well as a visual erroring 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.). Also, the ESU can be used in association with an ERBE compatible Argon Plasma Coagulator (APC). The unit is supplied non-sterile and is reusable.

Note: VIO stands for Variable Cut and Coagulation.

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Intended Use:

The ERBE ESU Model VIO 200 S is intended to deliver high frequency 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
The modified ESU (ERBE Model VIO 200 S) has the same intended use, protective circuits, and uses the same basic accessories (i.e. A/C Cord, Footswitches, Adapters, etc.) as the predicate ESU (ERBE Model VIO 300 D). Also, the available Modes [i.e. Auto Cut, Endo Cut Q, Endo Cut I, Soft Coag, Forced Coag, Bipolar Soft Coag with and without (Auto Stop] in the modified device are the same Modes that are in the predicate (Note: Some Modes have power limitations with the modified device as compared to the predicate.). Both Generators have user interface displays to select modes, power settings, etc. The modified and predicate devices are programmable and 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 compatible APCs with the respective APC being controlled through the ESU. Both models have the actual software for the APC within the ESU. The available APC related Modes (i.e., Forced APC as well as Argon-assisted Auto Cut, Forced Coag, and Soft Coag), for the modified device are the same as the predicate device (Note: Some Modes have power limitations with the modified device as compared to the predicate.). 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.).

Differences
The ERBE ESU Model VIO 200 S is different than the predicate VIO 300 D Model in that the modified ESU's display has Light Emitting Diodes (LEDs) for effect and wattage settings and it does not have an onscreen tutorial. However, it is easy for the user to interface with the display screen of the modified ESU. Also, there is a "Tutorial" section in its User Manual. There are less programming capabilities for the proposed device [nine (9) program possibilities] compared with 99 for the predicate ESU. However, only having 9 or less programs is adequate and there is less confusion with the smaller number. In regards to hardware features of the modified ESU, the unit was not designed with a Multi-Function (MF) module/receptacle and the associated specialty Mode (BiClamp) will not be offered with the modified device.

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The ERBE ESU Model VIO 200 S also is different than the ERBE VIO 300 D ESU in that the available wattage is less (i.e. 200 watts compared to 300 watts). However, a maximum 200 watt Generator has been found to be more than adequate (Note: The many ESUs on the U.S. market with maximum wattage being less than 200 watts.). With the limitation in power, the modified device doesn't have the capability of displaying the actual power delivered. Nonetheless, like the predicate device in the Cut and Coag Modes, the modified device still only delivers the amount of power needed.

Finally, there is no ReMode feature and less Modes with the modified device as compared to the predicate. Modes that are in the predicate and not in the modified device are High Cut, Dry Cut, Dry Cut °, Precise Cut, Swift Coag, Swift Coag °, Spray Coag, Precise Coag, Twin Coag, Bipolar Cut, Bipolar Cut +, Bipolar Precise Cut, Bipolar Soft Coag +, Bipolar Forced Coag, BiClamp, Bipolar Precise Coag, Precise APC, Pulsed APC, Argon-assisted High Cut, Argon-assisted Dry Cut, Argon-assisted Dry Cut °, Argon-assisted Swift Coag, Argon-assisted Swift Coag °, and Argon-assisted Twin Coag (Note: Only some of these Modes were standard with the predicate device.). Even though there are fewer modes within the ERBE Model VIO 200 S, the modes that are present are the principal ones to perform essential cutting and coagulating activities.

Conclusion:

The ERBE ESU Model VIO 200 S has the same intended use, principles of operation, and technological characteristics as the predicate ESU in the previously cleared 510(k). The modifications involve having a Generator that is more basic (i.e. less complicated with fundamental Modes thus having a more cost effective unit). Nonetheless, the modified ESU is an efficient unit. In conclusion, all the changes were verified or validated. As a result, the changes did not raise safety or efficacy concerns nor adversely affect safety or effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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ERBE USA, Inc.
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QA/RA Manager
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Marietta, Georgia 30067

APR - 2 2008

Re: K080715
Trade/Device Name: ERBE ESU Model VIO 200 S
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical cutting and coagulation device and accessories
Regulatory Class: II
Product Code: GEI
Dated: March 11, 2008
Received: March 13, 2008

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.

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): K080715

Device Name: ERBE USA, Inc.'s ERBE ESU Model VIO 200 S

Indications For Use:

The ERBE ESU Model VIO 200 S 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)

for mkm

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

510(k) Number K080715