K101108

510(k) SUMMARY

Submitted By: ERBE USA, Inc.
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JUL 16 2010

Contact Person: John Tartal
QA/RA Manager

Date Prepared: March 30, 2010

Common Name: ElectroSurgical Unit (ESU/Generator) System

Trade/Proprietary Name: ERBE ESU Model VIO 100 C with Accessories

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 200 S), 510(k) Number: K080715

Device Description:

Unit
The ERBE ESU Model VIO 100 C is a Generator 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 to provide the physician standard modalities in interventional applications (i.e. its ability to generate the HF current). The System has an automatic start feature. 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.). The Unit is supplied non-sterile and is reusable.

Note: VIO stands for Variable Cut and Coagulation.

Footswitches (Accessories)
Designated Footswitches have been developed for use with the ERBE ESU Model VIO 100 C. A Footswitch provides the physician a means to activate a mode of the ESU by depressing a foot pedal. There is a choice of two different types of Footswitches as follows:

VIO C One (Single) Pedal Coag Footswitch (Note: Activates coagulation mode.)
VIO C Two (Dual/Double) Pedal Footswitch (Note: Activates respectively cut and coagulation modes.)

Intended Use:

The ERBE ESU Model VIO 100 C 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 100 C) has the same intended use and uses the same basic accessories (i.e. A/C Cord, Adapters, Connecting Cables, etc.) as the predicate ESU (ERBE Model VIO 200 C). Both Units have a Monopolar, Bipolar, and Neutral Electrode Receptacle. Also, available modes [i.e., Auto Cut, Soft Coag, Forced Coag, Bipolar Soft Coag] in the modified device are the same Modes that are in the predicate (Note: Modes do not have effect settings and 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 the Auto Start feature with the Bipolar Soft Coag Mode. Also, each Unit has audio and visual error monitoring. The modified ESU is manufactured by ERBE Elektromedizin GmbH in Germany and like the predicate Generator will be supplied as non-sterile and is reusable. The packaging and labeling (e.g. Outer Package Label, User Manual, etc.) is similar for each device as well.

Differences
The ERBE ESU Model VIO 100 C is different than the predicate VIO 200 S Model in that the modified ESU is a basic Model with standard market features. It is lighter, smaller, and designed for use on a tabletop. Compared to the predicate device, the modified Unit has a Neutral Electrode Monitoring System which does not monitor the current density and symmetry of a split return electrode. However, the modified Unit monitors pad connection and with a split return electrode it monitors skin contact. Since the VIO 100 C provides less power than the predicate device, the monitoring system is adequate and according to the industry standard. Also, there are less programming capabilities [i.e., four (4) program possibilities] for the proposed device compared with nine (9) for the predicate ESU which makes the Unit less complicated.

The ERBE ESU Model VIO 100 C also is different than the ERBE VIO 200 S ESU in that the available wattage is less (i.e., 100 watts as compared to 200 watts). However, a maximum 100 watt Generator has been found to be adequate (Note: There are many ESUs on the U.S. market with maximum wattage being less than 100 watts.). The New Model also operates at slightly higher frequency (380 kHz) as compared to 350 kHz for the predicate device. Also there are no "Effect" settings for each of the modes with the modified Unit as compared to the predicate. Simply a power setting is used to increase or decrease the available wattage for delivery to target tissue (i.e., with a wattage setting increase, the effect is greater) for the modified ESU which eliminates the need for effect settings.

Modes that are in the predicate and not in the modified device are Endo Cut Q, Endo Cut I, and APC Forced as well as argon-assisted modes. An additional cut mode (Dry Cut) was included in the modified Unit as compared to the predicate (Note: This mode is in other 510(k) cleared ERBE ESU Models.). In summary, the modes in the ERBE Model VIO 100 C are principal ones to perform basic cutting and coagulating activities.

Finally, the ERBE ESU Model VIO 100 C also is different than the ERBE VIO 200 S ESU in that both Units have designated Footswitches. However, both of the ESU's Footswitches are made with similar materials and activate, via a foot pedal, cut as well as coagulation modes.

Conclusion:

The ERBE ESU Model VIO 100 C with Accessories has the same intended use, principles of operation, and similar 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) with designated Footswitches thus having a more cost effective System. 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
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

ERBE USA, Inc.
% Mr. John Tartal
2225 Northwest Parkway
Marietta, GA 30067

JUL 16 2010

Re: K101108
Trade/Device Name: ERBE ESU Model VIO 100 C with Accessories
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical cutting and coagulation device and accessories
Regulatory Class: II
Product Code: GEI
Dated: April 2, 2010
Received: April 20, 2010

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 go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. 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,

for

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

Enclosure

Indications for Use

510(k) Number (if known): _____

Device Name: ERBE USA, Inc.'s ERBE ESU Model VIO 100 C with Accessories

Indications For Use:

The ERBE ESU Model VIO 100 C 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)

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

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