K023886

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510K SUMMARY

Submitted By:	ERBE USA, Inc. 2225 Northwest Parkway Marietta, GA 30067 Tel: 770-955-4400 Fax: 770-955-2577
Contact Person:	John Tartal
Date Prepared:	11/18/02
Common Name:	Electrosurgical Generator (ESU) System
Trade/Proprietary Name:	ERBE VIO ESU (Model VIO 300 D) with Accessories
Classification Name:	Electrosurgical cutting and coagulation device and accessories (21CFR878.4400)
Product Code:	79GEI
Legally Marketed Predicate Device:	ERBE ERBOTOM ESU (Model ICC 350 E) 510(k) Number: K933002

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Device Description:

The ERBE VIO ESU with Accessories is an electrosurgical system that uses high frequency (hf) electrical current waveforms to cut and/or coagulate tissue.

Unit (Model VIO 300 D)

The ESU has a color monitor display that provides the user with an on-screen tutorial as well as setting 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., It's ability is 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 maybe 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.). Upon activation, the energy delivered (in watts) from the ESU to the tissue is displayed on the screen of the monitor. Also, the unit 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; whereas, ICC is Intelligent Cut and Coagulation.

Accessories (Components)

Connecting Cables- The Power Cord/Main Cable's function is to connect the ESU/system to the facilities' main power. The Monopolar Connecting Cable and the Return Electrode Connecting Cable are supplied to connect the ESU with the instruments and return electrodes (also referred to as patient plates/pads) utilized during the operative procedure. If the medical center has associated equipment (e.g., the VIO Cart), the Grounding Cable(s) link(s) the units together so that they all have a common ground.

Adapters- The Universal (Bovie-Jack) [also referred to as Monopolar] and Bipolar Adapters are for connecting universal/monopolar or bipolar instruments (via their cables) to the receptacles of the ESU. These Adapters provide the user the ability to utilize most of the instruments marketed for electrosurgical operative procedures.

Footswitches- A Footswitch provides the physician a means to activate a mode of the ESU by depressing a foot pedal. There is a choice of three different types of Footswitches available; the

VIO One (Single) Pedal Coag Footswitch (Note: Activates coagulation modes.),

VIO Two (Dual/Double) Pedal Footswitch (Note: Activates respectively cut and coagulation modes.), and

VIO Two (Dual/Double) Pedal Footswitch with ReMode (Note: Activates respectively cut and coagulation modes. It also has a "ReMode" feature that allows the physician to switch between two pre-programmed modes by using the button on the Footswitch rather than manually changing the modes by hand via the display of the ESU.).

Cart- The VIO Cart is the system carrier for the ESU and associated equipment. It has four (4) wheels, an internal storage area [Note: Primarily used for storing/housing argon gas cylinder(s)/regulator(s) if a compatible ERBE APC is a part of the system.], and electrical supply for power connections. It has a handle and a space for optional storage baskets or attaching other associated equipment.

All of the components are supplied non-sterile and reusable.

Intended Use:

The ERBE VIO ESU with Accessories is intended to deliver high frequency electrical current for the cutting and/or coagulation of tissue.

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

Unit (Model VIO 300 D)

Similarities

The modified ESU (ERBE Model VIO 300 D) has the same intended use and protective circuits as the predicate ESU (ERBE ERBOTOM Model ICC 350) with most of the same performance specifications. Both units 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. However, the actual software for the APC is within the modified ESU which is different than the predicate unit. The modified ESU is also manufactured by ERBE Elektromedizin GmbH in Germany and will be supplied as a non-sterile, reusable unit. The packaging and labeling (e.g., User Manual, etc.) components are similar except in the descriptions of the specific user instructions. The similarities and variations of the monopolar and bipolar modes are as follows.

Monopolar Modes:

The modified ESU has two (2) cut modes that are the same as the predicate ESU. They are the "Auto Cut" and the "High Cut" modes. However, the modified ESU has a larger voltage spread with eight (8) effect levels divided within the range where the predicate ESU only offers four (4) effect levels.

Both the modified and predicate ESUs have the same three (3) coagulation (coag) modes. The modes are "Soft Coag", "Forced Coag", and "Spray Coag". As with the cut modes, the modified ESU has a larger voltage spread with multiple effect levels divided within the spread [eight (8) for "Soft Coag", four (4) for "Forced Coag", and two (2) for "Spray Coag"]; whereas, the predicate ESU only offers one (1) effect level for each mode.

Bipolar Modes:

The modified and predicate ESUs have the same "Bipolar Cut" mode. But, a larger spread in voltage and more effect levels were included in the modified ESU. There are eight (8) effect levels in the modified unit in comparison to one (1) for the predicate ESU.

The same "Bipolar Soft Coag" mode is in the modified as well as the predicate device. However, the modified ESU has a larger voltage spread with eight (8) effect levels divided within the voltage spread; whereas, the predicate ESU only offers one (1) effect level over a smaller voltage range.

In conclusion, the larger voltage spread and more effect levels in the various modes were included with the modified ESU per request and feedback from doctors. The modifications were made to assist the user in obtaining the desired tissue effect for treating various patient conditions in a variety of interventional procedures. Nonetheless, the User Manual remains the same in the statement to the physician: "The power output setting should be set as low as possible for the desired tissue affect. The purpose of this is to help reduce the potential for capacitive coupling and inadvertent burning at higher wattages/voltages."

Differences

The modified ESU has a display monitor that features an on-screen tutorial, pictorial graphics illustrating modes and settings, as well as user information that defines the modes. The monitor also visually displays errors and defines error codes. These features aid medical personnel in the proper use of the unit and are not apart of the predicate device. Also, when the unit is activated, the actual power delivered (in watts) to tissue is displayed on the screen. The displayed value allows the user to evaluate the need to increase or decrease the wattage to obtain the desired tissue effect. Again, the predicate ESU does not display the actual power being delivered to tissue. Furthermore, the modules for the modified ESU are interchangeable; whereas, the predicate device has standard configured receptacles. This allows the user to have the exact features/functions (modes) that they need. Finally, the differences of the monopolar and bipolar modes are as follows.

Monopolar Modes:

The modified ESU in comparison to the predicate device has two (2) more cut modes; "Dry Cut" and "Precise Cut", but does not have the "Endo Cut" mode. "Precise Cut" is an optional mode. The "Dry Cut" mode has a larger voltage spread than prior cut modes. The properties of "Dry Cut" involve obtaining intense hemostasis with a somewhat slower cutting speed. For example, the properties of the mode are well suited for cutting through scar tissue. There are eight (8) effect levels in the "Dry Cut" mode. Very fine adjustments with a high-precision power output in a range from 1 to 50 watts are properties of the "Precise Cut" mode. The properties of this mode minimize the necrosis at the cut edge. There are eight (8) effect levels in the "Precise Cut" mode. At this time, the "Endo Cut" mode is in the predicate ESU and not in the modified device. With "Endo Cut" incisions are software controlled in such a way that short cuts are alternated with soft coagulation in the mode. Both of the properties are in separate modes of the modified ESU.

The modified ESU has two (2) more additional coagulation (coag) modes than the predicate ESU. They are the "Swift Coag" and "Precise Coag" modes. The "Precise Coag" mode is optional. The "Swift Coag" mode has a larger power spread than prior coagulation modes because the properties of "Swift Coag" involve obtaining a fast, effective coagulation, which is very suitable for dissection with high hemostasis, due to its limited tissue-cutting property. There are four (4) effect levels in the "Swift Coag Cut" mode. The "Precise Coag" properties involve having a very fine adjustment as well as high-precision power output in a range from 1 to 50 watts. There are eight (8) effect levels for the "Precise Coag" mode.

Bipolar Modes:

The modified ESU has one (1) additional standard bipolar coagulation (coag) mode, "Bipolar Forced Coag". This mode has a larger voltage spread than in prior coagulation modes to achieve faster bipolar coagulation.

The modified ESU has one other available bipolar coagulation mode, "BiClamp". The optional mode when used with a bipolar clamp affects a larger surface area than with the other bipolar modes. There are four (4) increasing effect levels. Adjustments can be made in relationship to the coagulation performance and the type of tissue that is involved.

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The additional modes in the modified ESU were included to meet the needs of physicians in obtaining desired tissue effects in a variety of interventional procedures and treatment of various patient conditions. Again, the statement to the physician in the User Manual is: "The power output setting should be set as low as possible for the desired tissue affect. The purpose of this is to help reduce the potential for capacitive coupling and inadvertent burning at higher wattages/voltages."

All the unit modifications have been verified or validated in design control.

Accessories (Components)

Connecting Cables
Similarities
The Main Cable/Power Cord, Monopolar Connecting Cable, and Return Electrode Connecting Cable are the same for the modified and predicate ESU.
Differences
The Grounding Cable for the modified ESU is slightly smaller and shorter in length (approximately 11" versus 19-1/2") in comparison to the predicate ESU. However, both Cables fit both systems and can be used interchangeably. The intended use and performance specifications are the same.

Adapters
Similarities
The Universal (Bovie-Jack) [Monopolar] Adapter is the same for the modified and predicate ESU.
Differences
The modified and predicate devices have the same Bipolar Adapter. However, the body of the Adapter was slightly changed so that it fits into the bipolar receptacle of both units.

Footswitches
Similarities
The Footswitches for the modified ESU are comparable to the predicate Footswitches in that they have the same intended use and performance specifications (except for the difference in the "ReMode" Footswitch described below), safety requirements (AP and IP X8 Equipment), packaging, and labeling. Also all of the Footswitches are provided non-sterile and are reusable.
Differences
The VIO Two (Dual/Double) Pedal Footswitch with ReMode has a "ReMode" button feature that allows a physician to use his foot to change between selected modes during a procedure.

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Cart

Similarities

The VIO Cart for the modified ESU in comparison to the Cart for the predicate ESU are the same in that they both house/carry their respective ESU and are used to store components and instruments. Both have handles. Dimensionally the Carts are very similar. Also, both are supplied non-sterile and reusable.

Differences

The modified VIO Cart has a larger wheelbase in comparison to the predicate. This gives added balance and stability when wheeling the cart over thresholds and elevator openings. The predicate Cart has shelves and a drawer; where as, the modified Cart has a storage cabinet and space for baskets. Also, the modified VIO Cart has electrical outlets and connection. This modification provides user with the means to centrally connect and ground all associated equipment.

All the modifications of the components have been verified or validated in design control.

Conclusion:

The ERBE VIO ESU (Model VIO 300 D) with Accessories has the same intended use, principles of operation, and technological characteristics as the predicate ESU in the previously cleared 510(k).

The modifications in the ESU involve having a more user friendly platform (e.g., adding a tutorial, providing setting/operational and error code information as well as displaying the actual power delivered to tissue on the monitor, etc.) and distinguishing further modes as well as having more defined effect levels in larger voltage ranges to assist the physician in interventional procedures to achieve desired tissue effect. Also, component changes involve meeting user needs (e.g., having ReMode on a Footswitch, electrical outlets on the Cart, etc.).

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
9200 Corporate Boulevard
Rockville MD 20850

DEC 1 2 2002

ERBE USA, Inc.
John Tartal
Manager, Quality Assurance/Regulatory Affairs
2225 Northwest Parkway
Marietta, Georgia 30067

Re: K023886
Trade/Device Name: ERBE VIO ESU (Model VIO 300 D) with Accessories
Regulation Number: 878.4400
Regulation Name: Electrosurgical cutting and coagulation device and accessories
Regulatory Class: Class II
Product Code: GEI
Dated: November 18, 2002
Received: November 21, 2002

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 Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Miriam C. Provost

for Celia M. Witten, Ph.D., MD
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) NUMBER (IF KNOWN): K023886

DEVICE NAME: Electrosurgical Generator (ESU) System (VIO ESU with Accessories)

INDICATIONS FOR USE:

High Frequency Electrical Current for the Cutting and/or Coagulation of Tissue

Miriam C. Provost

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

(510(k) Number K023886

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter-
(Per 21 CFR 801.109) (Optional Forma