

K073207

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5 510(k) Summary

MAY - 8 2008

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Establishment Registration Number: 3003724334

Date Prepared: April 25, 2008

510(k) Number: K073207

Common Name: Electrosurgical System

Trade Name: Olympus Electrosurgical System

Classification Name: Electrosurgical cutting and coagulation device and accessories
Regulation No: 878.4400
Product Code: GEI
Device Class: II

Legally Marketed Predicate Devices:	Trade Name	510(k)	Applicant
	Erbe VIO ESU (Model VIO 300 D) with Ac- cessories	K023886	Erbe USA, Inc.

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other display shows the currently selected program mode. Buttons are used to set the power level or to change the modes. Different connectors allow connecting mono- and bipolar electrosurgical instruments, a neutral electrode, a footswitch, or an ancillary pump. The maximum output power is 120 W.

Application Modes:

Monopolar Cut: Three continuous cutting modes (*Cut 1*, *Cut 2*, and *Cut 3*) for standard tissue cutting; two intermittent cutting modes (*PulseCut Slow* and *PulseCut Fast*) for slow and controlled tissue cutting.

Monopolar Coagulation: One mode for standard coagulation procedures (*SoftCoag*); two modes for forced coagulation (*ForcedCoag 1*, *ForcedCoag 2*).

Bipolar Cut: Three continuous cutting modes for standard tissue cutting applications (*Cut 1*, *Cut 2*, and *Cut 3*).

Bipolar Coagulation: Three bipolar coagulation modes (*SoftCoag*, *RFCoag*, *RFCoag + RCAP*). *SoftCoag* is used for standard coagulation and hemostasis. *RFCoag* is used for controlled coagulation. It features acoustic resistance feedback and an automatic end of procedure detection. *RFCoag + RCAP* is especially suited for deep tissue coagulation without significant tissue desiccation; it also features an end of procedure detection.

The modes have preset power levels that may be customized by the user in a defined range.

Design:

The design of the Olympus ESG-100 complies with the following standards:

IEC 60601-1
UL 60601-1
IEC 60601-1-2
IEC 60601-1-4
IEC 60601-1-6
IEC 60601-2-2
ISO 14971

Olympus AFU-100

The AFU-100 peristaltic flushing pump employs tubing to deliver fluid to the tissue/mucosa. Sterile liquids (e.g. isotonic saline solution) thus remain sterile, provided that a sterile tube set is used.

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The maximum flow rate is 270 ml and 600 ml per minute with two different tube sets offered as single use items (see Figure 2). In addition, three memory buttons provide fast access to preset flow levels. The AFU-100 can be connected to the electrosurgical generator ESG-100 by an interface, allowing operation of the peristaltic pump unit by a special button of the electrosurgical unit's footswitch.

The pump rotor is equipped with a protective cover, which automatically stops the rollers from rotating if it is opened while the peristaltic pump unit is activated, and thus prevents possible injuries.

Design:

The design of the Olympus AFU-100 complies with the following standards:

IEC 60601-1
UL 60601-1
IEC 60601-1-2
IEC 60601-1-4
IEC 60601-1-6
ISO 14971

Accessories

A-Cord: The A-cord is used to connect active instruments to the Olympus ESG-100.

P-Cord: The P-cord is used to connect a neutral electrode to the Olympus ESG-100.

Footswitch (ESG-100): The footswitch of the ESG-100 is connected with a cable to the generator. It has a yellow CUT and a blue COAG pedal. An additional button allows switching between the application modes or to activate the pump flow, if an ancillary pump unit is connected.

Footswitch (AFU-100): The footswitch is an optional accessory to the AFU-100. It has one pedal to activate and deactivate the pump.

Pump Tube: There are two different sizes of pump tubes available. The tubes are inserted into the pump head and connect the liquid source with the surgical instrument.

Intended Use:

The Olympus Electrosurgical System is an electrosurgical system consisting of the Olympus ESG-100 electrosurgical generator, in conjunction with the footswitch and the peristaltic flushing pump Olympus AFU-100. The Olympus ESG-100 is designed to perform monopolar and bipolar functions in the operating arena. The AFU-100 flushing pump is intended for irrigation of instruments or irrigation/flushing/cleansing of tissue surfaces and wounds supporting endoscopic diagnosis or therapy.

Comparison to Predicate Devices:

The Olympus Electrosurgical System has the same indication statement as the predicate system consisting of ERBE VIO 300 D with Ac-

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cessories and ERBE EIP 2. In addition, these two systems have similar technological characteristics.

The subject ESG-100 has the same indication statement, the same intended use statement and similar technological characteristics as the predicates ICC 200 and VIO 300 D.

The ENDO CUT mode of the predicate ICC 200 offers an equivalent to the *PulseCut slow / fast* of the subject ESG-100. The predicate VIO 300 D and the subject ESG-100 are suitable for bipolar cutting. There are minor differences in the output characteristics and the quantity of the application modes, the maximum output power, or the handling, but they do not change the safety and effectiveness or result in new potential risks.

The subject Olympus AFU-100 has the same indication statement and similar technological characteristics as the predicate Olympus OFP-1. It also has the same intended use and technological characteristics as the Erbe EIP 2. However, the EIP 2 has been registered under a different product code. Nevertheless the intended use statements and the technological characteristics of the predicates EIP 2 and OFP-1 are substantial equivalent to the Olympus AFU-100.

Conclusion:

The data show that the differences between the subject Olympus Electrosurgical System and the predicate devices do not affect the safety and effectiveness, as no changes were incorporated in the intended use, in the performance, and in the physical principles that the system is based upon. Therefore, no additional tests are necessary for evaluation of safety and efficacy. Nevertheless bench tests of the subject ESG-100 and the predicate devices ICC 200 and VIO 300 D were performed and demonstrate substantial equivalence.



Food and Drug Administration
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MAY - 8 2008

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Re: K073207

Trade/Device Name: Olympus Electrosurgical System
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical cutting and coagulation device and accessories
Regulatory Class: II
Product Code: GEI, FEQ
Dated: April 29, 2008
Received: May 5, 2008

Dear Ms. Storms-Tyler:

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

4 Indications for Use

510(k) Number (if known): K073207

Device Name: *Olympus Electrosurgical System*

Indications For Use:

The Olympus Electrosurgical System is an electrosurgical system consisting of the Olympus ESG-100 electrosurgical generator, in conjunction with the footswitch and the peristaltic flushing pump Olympus AFU-100. The Olympus ESG-100 is designed to perform monopolar and bipolar functions in the operating arena. The AFU-100 flushing pump is intended for irrigation of instruments or irrigation/flushing/cleansing of tissue surfaces and wounds supporting endoscopic diagnosis or therapy.

Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(21 CFR 801 Subpart C)

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

Neil R. P. Oden for mxm
Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)

**Division of General, Restorative,
and Neurological Devices**

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510(k) Number K073207