November 29, 2018

Olympus Winter & Ibe GmbH
% Dolan Mills
Senior Specialist, Regulatory Affairs
Gyrus ACMI, Inc.
136 Turnpike Road
Southborough, Massachusetts 01772

Re: K182587
Trade/Device Name: Device Electrosurgical Generator ESG-150
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical Cutting and Coagulation Device and Accessories
Regulatory Class: Class II
Product Code: GEI
Dated: September 19, 2018
Received: September 20, 2018

Dear Dolan Mills:

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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 comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Long H. Chen -S

Digitally signed by Long H. Chen -S
Date: 2018.11.29 10:22:54 -05'00'

for

Binita S. Ashar, M.D., M.B.A., F.A.C.S.
Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*

K182587

Device Name
Electrosurgical generator ESG-150

Indications for Use *(Describe)*
The electrosurgical generator, in conjunction with electrosurgical accessories and ancillary equipment, is intended for cutting and coagulating tissue in endoscopic surgery.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) Summary

2.1 General Information

Manufacturer: Olympus Winter & Ibe GmbH
Kuehnstr. 61
22045 Hamburg
Germany

Establishment Registration Number: 9610773

Official Correspondent: Dolan Mills
Senior Specialist, Regulatory Affairs
Gyrus ACMI, Inc.
136 Turnpike Rd.
Southborough, MA 01772
Phone: (901) 373-0236
Email: dolan.mills@olympus-osta.com

Establishment Registration Number: 3003790304

Date Prepared: Sep 19, 2018

2.2 Device Identification

Proprietary name:	Electrosurgical Generator ESG-150
Device Classification name:	Electrosurgical cutting and coagulation device and accessories
Regulation Medical Specialty:	General & Plastic Surgery
Regulations Number:	21 CFR 878.4400
Regulatory class:	Class II
Product code:	GEI

2.3 Predicate Device

The subject device, ESG-150, is considered substantially equivalent to the legally marketed device of K141225, GEI, 21CFR 878.4400:

Olympus ESG-400

No reference devices were used in this submission.

2.4 Product Description

The ESG-150 is a reusable, non-sterile electrosurgical generator that features different monopolar and bipolar cutting and coagulation modes. The maximum output power is 120 W. It is intended for cutting and coagulation of tissue in endoscopic surgery in conjunction with electrosurgical accessories and ancillary equipment.

The generator is a class II medical device under the regulation number 878.4400 and the product code GEI – "Electrosurgical cutting and coagulation device and accessories" Regulation Medical Specialty: General & Plastic Surgery.
It is compliant with FDA recognized consensus safety standards as listed in section III, Appendix III - Standard Conformity and Test Reports.

The front panel of the ESG-150 features a touch screen GUI (graphical user interface) and all settings of the device (e.g. selecting the socket, selecting the mode, increasing/decreasing power and effect, recalling user settings, etc.) are done via the touchscreen on the front panel. The mode is selected according to the type of procedure that will be performed and according to the HF instruments that will be used.

The ESG 150 has three contact quality indicators (CQM); green, red and grey which indicate the connection status of the neutral electrode. Green highlights that a split neutral electrode is correctly connected, red highlights that the split neutral electrodes is not connected sufficiently, and grey indicates that a non-split neutral electrode is connected, or that a split type neutral electrode is connected but is not recognized by the CQM, or is performing incorrectly (short circuit). The generator can store selectable settings, e.g. Power and Effect, and allows the user to adjust the volume of touch screen buttons and activation either with the volume control on the rear panel or via touchscreen (this does not apply to alarm signals).

In addition to the GUI, the ESG-150 has a bipolar socket, a monopolar socket (B Type), and a neutral electrode socket. The power switch turns the generator on and off. The rear panel includes the volume control, a ventilation hole, the equipotential bonding point, the AC power socket, and a footswitch socket.

2.5 Indications for Use

"The electrosurgical generator, in conjunction with electrosurgical accessories and ancillary equipment, is intended for cutting and coagulating tissue in endoscopic surgery."

2.6 Technological Characteristics

The ESG-150 has the same intended use and technological characteristics as the predicate device ESG-400, however, the ESG 400 is indicated for both open and laparoscopic surgery in addition to endoscopic.

While various instruments can be connected to the monopolar and bipolar sockets, because the PK modes of the predicate device (K141225) are not integrated in the ESG-150, the flare out detection is not applicable. The basic design philosophy of the User Interface (UI) and GUI flow chart concept is identical, except for the special ESG-400 amendment in regard to the PK instruments.

In comparison to the primary predicate device the following output modes are available:

2.6.1 Output modes in comparison to the primary predicate device ESG-400

Subject Device: ESG-150	**Predicate Device: ESG-400**
PureCut	PureCut
PulseCut Slow	PulseCut slow
PulseCut Fast	PulseCut fast
N/A	Blend Cut
N/A	PureCut
N/A	FineCut

Table 2.1: Monopolar Cut Modes

Subject Device: ESG-150	**Predicate Device: ESG-400**
SoftCoag	SoftCoag
ForcedCoag	ForcedCoag
N/A	PowerCoag
N/A	SprayCoag

Table 2.2: Monopolar Coagulation Modes

Subject Device: ESG-150	Predicate Device: ESG-400
BipolarCut	BipolarCut
N/A	SalineCut
N/A	PK PureCut
N/A	PK SoftCut
N/A	PK LoopCut
N/A	PK MorceCut

Table 2.3: Bipolar Cut Modes

Subject Device: ESG-150	Predicate Device: ESG-400
BiSoftCoag	BiSoftCoag
N/A	RFCoag
N/A	AutoCoag
N/A	SalineCoag
N/A	HardCoag
N/A	FineCoag
N/A	PK Coag
N/A	PK Softcoag
N/A	PK AutoCoag

Table 2.4: Bipolar Coagulation Modes

The range of output waveforms is identical but the power levels are decreased in comparison to the FDA cleared ESG-400 electrosurgical generator, K141225.

2.7 Substantial Equivalence

Substantial equivalence is demonstrated by acknowledged verification/validation methodologies. The subject device has equivalent technology, performance, dimensions and materials. The differences to the primary predicate device ESG-400 are:

- only one monopolar socket, no universal socket, no docking station interface on the bottom
- to be used only in conjunction with a double pedal footswitch
- new enclosure
- no PK instruments incorporation
- GUI modifications (additional strings, languages, sounds, screens, windows)
- more effect levels available for most ESG-150 Modes than for the predicate

2.8 Performance Data

The following performance data were provided in support of the substantial equivalence determination. All standards applied are FDA recognized international standards.

The data was prepared in accordance with the FDA guidance, Premarket Notification (510(k)) Submissions for Electrosurgical Devices for General Surgery Guidance for Industry and Food and Drug Administration Staff, issued on August 15, 2016. The guidance was followed for all relevant sections.

2.8.1 Biocompatibility testing

The ESG-150 and its accessories do not contain components that come directly or indirectly into patient contact. Biocompatibility testing according to ISO 10993 is not required.

2.8.2 Electrical safety and electromagnetic compatibility (EMC)

The design of the ESG-150 complies with recognized standards as listed in section 2.8.8 of this summary.

The FDA guidance "Information to Support a Claim of Electromagnetic Compatibility (EMC) of Electrically-Powered Medical Devices", CDRH July 11, 2016 has been followed.

2.8.3 Thermal Safety

The design of the ESG-150 complies with recognized standards as listed in section 2.8.8 of this summary.

2.8.4 Animal and Clinical Studies

Clinical and animal studies were not necessary.

2.8.5 Software

The software validation activities were performed in accordance with the FDA Guidance, "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices" (May 11, 2005), and in accordance with the FDA Guidance: "Premarket Notification (510(k)) Submissions for Electrosurgical Devices for General Surgery" (Aug. 15, 2016). This device type software presents a "Major Level of Concern".

2.8.6 Performance Testing Bench

To demonstrate substantial equivalence, the following aspects were considered within the validation versus the predicate devices.

1. Performance and validation tests incorporated the same range of waveform outputs and power levels.
2. During the validation testing the waveforms and test results were compared directly between the subject and predicate device

Basic safety and performance testing was performed in accordance with IEC standards. In addition, verification and comparison bench studies were conducted to evaluate the functional performance.

Preclinical: Evidence obtained from preclinical simulated use studies demonstrate that the device performs substantially equivalent to the predicate device in relevant aspects associated with usability, tissue effects, and thermal effects. For simulated use testing, three clinically relevant tissue types were evaluated in all applicable modes: porcine muscle, liver, and kidney. The tissue effects testing included quantitative and qualitative assessment.

In accordance with FDA Guidance, Premarket Notification (510(k)) Submissions for Electrosurgical Devices for General Surgery, the thermal damage of the tissue due to the HF current was measured in terms of size (length, width and depth) of the thermal coagulation zone. Furthermore, each test included the minimum, default and maximum intensity settings. All modes were compared to the predicate. Where the minimum or maximum intensity settings of the test and predicate device differed in terms of output wattage by specification the closest applicable settings were chosen.

These comprehensive validation bench tests support equivalence to the predicate device. Testing confirmed that comparable tissue effects could be achieved for applicable modes of operation with three tissue types.

Usability and user interface was also assessed according to the risk management plan. The assessment was based on Olympus predecessor product. Use-related hazardous situations were assessed and risk mitigation measures in terms of usability design for safety were defined. The residual risk was evaluated as acceptable.

Risk analysis was carried out in accordance with established internal acceptance criteria based on ISO 14971:2007.

2.8.7 Reprocessing

Required cleaning, disinfecting and drying procedures are described in the instructions for use.

2.8.8 Applied standards

Standard No.	Standard Title	FDA-Recognition no + date
AAMI/ANSI ES 60601-1:2005/(R)2012 and C1:2009/(R)2012 and, A2:2010/(R)2012	Medical electrical equipment - Part 1: General requirements for basic safety and essential performance (IEC 60601-1:2005, MOD)	19-4 07/09/2014
IEC 60601-1-2 Edition 4.0 2014	Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests	19-8 06/27/2016
IEC 60601-1-8 Ed. 2.1: 2012	Medical electrical equipment - Part 1-8: General requirements for basic safety and essential performance - Collateral Standard: General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems	5-76 08/05/2013
ANSI AAMI IEC 60601-2-2:2009	Medical Electrical Equipment - Part 2-2: Particular Requirements For The Basic Safety And Essential Performance Of High Frequency Surgical Equipment And High Frequency Surgical Accessories	6-389 08/21/2017
IEC 62304 62304 Edition 1.1 2015-06	Medical device software - Software life cycle processes	13-79 04/04/2016
IEC 60601-1-6 Edition 3.1 2013-10	Medical electrical equipment Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability	5-89 06/27/2016
ISO 14971 Second edition 2007	Medical devices - Application of risk management to medical devices	5-40 06/27/2016
IEC 62366-1 Edition 1.0 2015-02	Medical Devices - Part 1: Application Of Usability Engineering To Medical Devices [Including CORRIGENDUM 1 (2016)]	5-114 12/23/2016

Table 2.5: Applied standards

2.9 Conclusion

The performance data support the safety of the device and demonstrate that the subject device complies with the recognized standards as specified.

In summary, we believe the ESG-150 is substantially equivalent with the predicate device with respect to the general design approach, function, and the intended use. The ESG-150 raises no new concerns of safety or effectiveness when compared to the predicate device.