August 18, 2023

Olympus Winter & Ibe GmbH
% Mr. Dolan Mills
Program Manager, Regulatory Affairs
Olympus Surgical Tech. America;
Gyrus ACMI, Inc.
800 West Park Drive
Westborough, Massachusetts 01581

Re: K231777
Trade/Device Name: ESG-410 (Models: WA91327U, WA91327W)

Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical cutting and coagulation device and accessories
Regulatory Class: Class II
Product Code: GEI
Dated: June 16, 2023
Received: June 16, 2023

Dear Mr. 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/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); 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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). 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 (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Mark Trumbore -S

Digitally signed by Mark Trumbore -S
Date: 2023.08.18 09:21:24 -04'00'

Mark Trumbore, Ph.D.
Assistant Director
DHT4A: Division of General Surgery Devices
OHT4: Office of Surgical
and Infection Control Devices
Office of Product Evaluation and Quality
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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K231777

Device Name
ESG-410 (Models: WA91327U, WA91327W)

Indications for Use *(Describe)*

The electrosurgical generator, in conjunction with compatible devices and electrosurgical accessories, is intended for cutting and coagulation of soft tissue and for ligation of vessels. The electrosurgical generator utilizes monopolar and bipolar high frequency current and supports ultrasonic instruments.
The electrosurgical generator is intended to be used in the following medical fields:

- Open surgery
- Laparoscopic surgery, including single-site surgery
- Endoscopic surgery

Only for use by a qualified physician in an adequate medical environment.

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.

2 510(k) Summary

2.1 General Information

Applicant:	Olympus Winter & Ibe GmbH Kuehnstrasse 61 22045 Hamburg Germany Establishment Registration Number: 9610773
Manufacturer:	Olympus Winter & Ibe GmbH Berlin Facility Rheinstrasse 8 14513 Teltow Germany Establishment Registration Number: 3003724334
510(k) Correspondent:	Mr. Dolan Mills Program Manager, Regulatory Affairs Olympus Surgical Tech. America Gyrus ACMI, Inc. 800 West Park Drive Westborough, MA 01581 Phone: (901) 355-0007 Email: dolan.mills@olympus.com Establishment Registration Number: 3003790304
Date prepared:	Aug 15, 2023

2.2 Device Identification

Tradename:	ESG-410 (Models: WA91327U, WA91327W)
Footswitch Model numbers:	WA91311W, WA91321W
Classification Number:	21 CFR 878.4400
Classification name:	Electrosurgical cutting and coagulation device and accessories
Product code:	GEI
Regulatory class:	Class II
Review Panel:	General & Plastic Surgery

2.3 Predicate Device

The electrosurgical generator ESG-410 and accessories are considered substantially equivalent to the following legally marketed devices:

Predicate Device		Manufacturer	510(k) No.
Primary Predicate	Electrosurgical Generator ESG-410 and Accessories	Olympus Winter & Ibe GmbH	K203277
Secondary Predicate	Olympus ULTRASONIC BIPOLAR GENERATOR USG-410	OLYMPUS MEDICAL SYSTEMS	K211838

Table 2.1: Identification of predicate device

2.4 Product Description

The subject device ESG-410 is a reusable, non-sterile electrosurgical generator that features different high frequency monopolar and bipolar cutting and coagulation modes with a maximum output power of 320 W, as well as capability to power the existing Olympus ultrasonic THUNDERBEAT and SONICBEAT devices via a redesigned HYBRID ULTRASONIC socket and four new modes using high frequency (RF bipolar output) energy and supporting ultrasonic energy. The maximum RF output power for the THUNDERBEAT mode is 110 W.

The electrosurgical generator, in conjunction with compatible devices and electrosurgical accessories and ancillary equipment, is intended for cutting and coagulation of soft tissue in open surgery, laparoscopic surgery (including single-site surgery), endoscopic surgery and for ligation of vessels. The electrosurgical generator utilizes monopolar and bipolar high frequency current and supports ultrasonic instruments.

The front panel of the proposed ESG-410 features a touch screen GUI (graphical user interface) as well as the power switch (on/off), six output sockets and one neutral electrode socket.

The touch screen GUI displays the current settings of the chosen output mode, the connection status of accessories and peripherals connected to the electrosurgical generator. Soft keys are integrated into the GUI to switch between the output sockets, to enter the menu in order to edit settings/procedures (e.g. create/ edit user-defined settings/ procedures), to edit preferences (e.g. select language, touch tone control, output volume, or brightness) and to show service options (e.g. software version identifier, for service and maintenance purposes) or to access user-defined settings and procedures.

It is compliant with FDA recognized consensus safety standards as listed in section 2.8.8 below.

2.5 Indications for Use

The electrosurgical generator, in conjunction with compatible devices and electrosurgical accessories, is intended for cutting and coagulation of soft tissue and for ligation of vessels. The electrosurgical generator utilizes monopolar and bipolar high frequency current and supports ultrasonic instruments.

The electrosurgical generator is intended to be used in the following medical fields:

- Open surgery
- Laparoscopic surgery, including single-site surgery
- Endoscopic surgery

Only for use by a qualified physician in an adequate medical environment.

2.6 Technological Characteristics

The subject ESG-410 has an equivalent intended use and technological characteristics as the primary predicate device ESG-410 (K203277).
Various instruments can be connected to the two monopolar sockets or one bipolar socket as well as to the two universal sockets. In addition, dedicated Olympus instruments or Olympus cables can be connected to the two universal sockets with instrument recognition.
The basic design philosophy of the User Interface (UI) and GUI flow chart concept is equivalent. Compared to the predicate ESG-410 (K203277), the ESG-410 subject to this submission offers four additional output modes which are equivalent to the modes in the secondary predicate device USG-410 (K211838). Furthermore, the GUI of 2 existing modes from the primary predicate (K203277) adds level 1-5 as an alternative to the existing power/effect settings. The new level concept does not exceed the predicate power/effect settings. It provides another option to deliver an easy setup for users to account for user preference.

The capability to connect THUNDERBEAT and SONICBEAT devices via the HYBRID ULTRASONIC socket is equivalent to the function provided by the secondary predicate device USG-410 (K211838).

2.6.1 Output modes in comparison to the primary predicate device ESG-410

The range of bipolar and monopolar output waveforms and the power levels are identical in comparison to the predicate ESG-410 electrosurgical generator, K203277.

2.6.2 Output modes in comparison to the secondary predicate device USG-410

The range of ultrasonic and high frequency output waveforms and the power levels are equivalent in comparison to the secondary predicate USG-410 electrosurgical generator, K211838.

2.7 Substantial Equivalence

Substantial equivalence is demonstrated by acknowledged verification/validation methodologies. The subject devices have equivalent technology, performance, dimensions, and materials. The differences from the primary predicate device ESG-410 (K203277) are:

- One HYBRID ULTRASONIC socket, compared to one Surgisaber socket
- The GUI is modified to support the four new modes.

- The GUI is modified to integrate the new level concept of two modes.
- Intelligent Tissue Monitoring (ITM) is provided for two modes used in conjunction with THUNDERBEAT and SONICBEAT devices to detect small impedance changes of ultrasonic vibrations, so that the electrosurgical generator is able to automatically stop the output after the target tissue is divided.

To support the additionally implemented HYBRID ULTRASONIC socket and the additional four modes using high frequency (RF bipolar output) energy and supporting ultrasonic energy, a secondary predicate device has been selected. Substantial equivalence for the secondary predicate device is demonstrated by acknowledged verification/ validation methodologies. The secondary predicate device has equivalent technology and performance in respect to the compared modes.

There have been no changes to the technological characteristics or intended use of the predicate devices since its clearance.

The intended use for the subject device in comparison to the primary predicate ESG-410 (K203277) is complemented by the ability to support ultrasonic instruments by way of the secondary predicate USG-410 (K211838). The indication wording differences do not represent an extension of the indications for use but add clarity to the indications for use that are already covered by the predicates.

The basic compatibility testing and electrical testing demonstrate equivalence.

Items of Comparison	**Subject device: ESG-410 and accessories**	**Primary Predicate Device: ESG-410 and accessories (K203277)**	**Secondary Predicate device: USG-410 (K211838)**	**Evaluation of differences**
Device Name	Electrosurgical Generator ESG-410 and Accessories	Electrosurgical Generator ESG-410 and Accessories	USG-410 Ultrasonic Bipolar Generator	Same
Regulation Specialty	General & Plastic Surgery	General & Plastic Surgery	General & Plastic Surgery	Identical
Device Classification Name	Electrosurgical cutting and coagulation device and accessories	Electrosurgical cutting and coagulation device and accessories	Electrosurgical cutting and coagulation device and accessories	Identical
Intended Use/ Indications for Use	Intended for cutting and coagulation of soft tissue and for ligation of vessels. • Open surgery	Intended for cutting and coagulation of tissue: • Open surgery • Laparoscopic surgery	Intended for open, laparoscopic (including single-site surgery), and endoscopic surgery to cut (dissect) or	Same in total

Items of Comparison	Subject device: ESG-410 and accessories	Primary Predicate Device: ESG-410 and accessories (K203277)	Secondary Predicate device: USG-410 (K211838)	Evaluation of differences
	• Laparoscopic surgery, including single-site surgery • Endoscopic surgery	• Endoscopic surgery	coagulate soft tissue or to ligate (seal and cut) vessels.	

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.

All 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 March 9, 2020. The guidance was followed for all relevant sections.

2.8.1 Biocompatibility testing

The ESG-410 and foot switches do not come into direct or indirect patient contact. Therefore, biocompatibility evaluation and testing according to ISO 10993-1 is not required.

2.8.2 Electrical safety and electromagnetic compatibility (EMC)

The design of the ESG-410 complies with recognized standards as listed in section 2.8.8 below.

The FDA guidance, Electromagnetic Compatibility (EMC) of Medical Devices, Guidance for Industry and Food and Drug Administration Staff, issued June 6, 2022, has been followed.

2.8.3 Thermal Safety

The design of the ESG-410 complies with recognized standards as listed in section 2.8.8 below.

2.8.4 Clinical and animal Studies

Clinical and animal studies were not necessary to prove equivalence.

This determination was based on the test results obtained during the non-clinical bench testing, which confirmed:

i. Vessel Burst Pressure: The burst pressure in vessels (veins and arteries) of test article (subject device) is higher than or not statistically significantly different from those of control groups.

ii. Thermal Spread: The thermal spread in vessels of test article (subject device) is smaller than or not statistically significantly different from those of control groups.

2.8.5 Software

The subject ESG-410 generator contains 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). The device software is considered a “Major Level of Concern”. Furthermore, the FDA Guidance, “General Principles of Software Validation; Final Guidance for Industry and FDA Staff”, issued January 11, 2002 was followed.

As parts of the software are off-the-shelf software. The guidance “Off-The-Shelf Software Use in Medical Devices” Guidance for Industry and Food and Drug Administration Staff, issued on September 27, 2019, was taken into account for the relevant sections.

To fulfill the requirements with regard to cybersecurity the FDA Guidance document “Content of Premarket Submissions for Management of Cybersecurity in Medical Devices, issued October 02, 2014” was followed. Cybersecurity is documented according to AAMI TIR57 “Principles for medical device security – Risk management”, 2016. The wired foot switches which are subject to this submission do not contain software.

2.8.6 Performance Bench Testing

To demonstrate substantial equivalence the following aspects were considered within the verification and 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 tissue effects were compared directly between the subject and predicate devices.

Bench testing supports the claim of substantial equivalence to the predicate devices. The validation plan specifies modes, instruments and test protocols/plans for tissue effects and electrical waveforms. Beside tissue effects, the waveforms of the generators were compared. For all modes the tests demonstrated comparable tissue effects and electrically comparable waveforms.

The following non-clinical and preclinical tests were conducted:

1) non-clinical (electrical, dimensional, functional, stability),
2) preclinical (simulated use) evaluation and testing of tissue effects and thermal safety

Non-clinical: 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.

Testing of equivalence was performed in comparison to the predicate devices in relevant aspects associated with usability, tissue effects, and thermal effects.

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

Usability and user interface were 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 14971:2019.

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 & A1:2012, C1:2009/(R)2012 & A2:2010/(R)2012 (Cons. Text) [Incl. AMD2:2021]	Medical electrical equipment - Part 1: General requirements for basic safety and essential performance (IEC 60601-1:2005, MOD) [Including Amendment 2 (2021)]	19-46 05/30/2022
ANSI/AAMI/ES 60601-1:2005/(R)2012 and C1:2009/(R)2012 and, A2:2010/(R)2012 (Consolidated Text)	Medical electrical equipment - Part 1: General requirements for basic safety and essential performance (IEC 60601-1:2005, MOD)	19-4 07/09/2014 (foot switches)
ANSI/AAMI/IEC 60601-1-2:2014 [including AMD 1:2021]	Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests [including Amendment 1 (2021)]	19-36 12/21/2020
ANSI/AAMI/IEC 60601-1-8:2006 and A1:2012 [Including AMD 2:2021]	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 [Including Amendment 2 (2021)]	5-131 12/21/2020
ANSI/AAMI/IEC 60601-2-2:2017	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 06/07/2021
IEC 62304 Edition 1.1 2015-06 CONSOLIDATED VERSION	Medical device software - Software life cycle processes	13-79 01/14/2019
IEC 60601-1-6 Edition 3.2: 2020-07 CONSOLIDATED VERSION	Medical electrical equipment Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability	5-132 12/21/2020
IEC 62366-1 Edition 1.1 2020-06 CONSOLIDATED VERSION	Medical devices – Part 1: Application of usability engineering to medical devices	5-129 07/06/2020

Standard No.	Standard Title	FDA-Recognition no + date
ISO 14971 Third Edition 2019-12	Medical devices – Application of risk management to medical devices	5-125 12/23/2019
ASTM D4169-22	Standard Practice for Performance Testing of Shipping Containers and Systems	14-576 05/30/2022
ASTM D4332-14	Standard Practice for Conditioning Containers, Packages, or Packaging Components for Testing	5-99 04/04/2016

Table 2.2: Applied standards

2.9 Conclusion

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

In summary, we believe the ESG-410 and accessories are substantially equivalent with the predicate devices with respect to the general design approach, function, and the intended use. The ESG-410 and accessories raise no new concerns of safety or effectiveness when compared to the predicate devices.