DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

May 4, 2016

Olympus Winter & Ibe GmbH
% Mr. Graham Baillie
Manager, Regulatory Affairs
Gyrus ACMI, Inc.
136 Turnpike Rd.
Southborough, Massachusetts 01772

Re: K160639
Trade/Device Name: Olympus ESG-200 Electrosurgical Generator: (CELON Elite WA90001A, WA90002A and CELON Precision WA90008A, WA90009A)
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical cutting and coagulation device and accessories
Regulatory Class: Class II
Product Code: GEI
Dated: March 2, 2016
Received: March 7, 2016

Dear Mr. Baillie:

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 contact the Division of Industry and Consumer Education 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. 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 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 Industry and Consumer Education 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,

Jennifer R. Stevenson -A

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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K160639

Device Name
Olympus ESG-200 Electrosurgical Generator: (CELON Elite WA90001A WA90002A and CELON Precision WA90008A, WA 90009A)

Indications for Use *(Describe)*
Electrosurgical generator intended for tissue cutting and coagulation in conjunction with electrosurgical accessories and ancillary equipment.

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"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

May 4, 2016
K160639

General Information

Manufacturer: Olympus Winter & Ibe GmbH
Kuehnstr. 61
22045 Hamburg, Germany
Establishment Registration Number: 9610773

Official Correspondent: Graham A.L. Baillie, MS
Manager, Regulatory Affairs
Gyrus ACMI, Inc.
136 Turnpike Rd.
Southborough, MA 01772-2104
Phone: 508.804.2738
Fax: 508. 804.2624
Email: Graham.baillie@olympus-osta.com
Establishment Registration Number: 3003790304

Device Identification

Proprietary name: Olympus ESG-200 Electrosurgical Generators: (CELON Elite WA90001A, WA90002A and CELON Precision WA90008A, WA90009A)
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

Predicate Device

Both variants (CELON PRECISION / CELON ELITE) of the proposed ESG-200 are considered substantially equivalent to the following legally marketed device:

- **Olympus ESG-400 (Primary Predicate, K141225)**

Both ESG-200 variants also have two secondary predicates for specific features as identified below:

Subject device variant	Secondary predicate	510(k) No
CELON PRECISION ESG-200	VNUS Radiofrequency Generator, Model RFG2	K040638
CELON ELITE ESG-200	Celon Lab ENT	K032838

Table 2.1: secondary predicate devices for a few specific features

Device Description

The Olympus ESG-200 Electrosurgical Generators: (CELON Elite WA90001A, WA90002A and CELON Precision WA90008A, WA90009A), including its two variants the Celon Elite and Celon Precision are reusable, non-sterile electrosurgical generators that feature different mono- and bipolar cutting and coagulation modes. The maximum output power is 120 W. Both variants of the ESG-200 are intended for cutting and coagulation of tissue in open, laparoscopic and endoscopic surgery in conjunction with electrosurgical accessories and ancillary equipment.

The front panels of the proposed ESG-200 features a touch screen GUI (graphical user interface) that displays the connection status of accessories and peripherals connected to the electrosurgical generator. Two contact quality indicators (one for split and one for non-split electrodes) are green illuminated if neutral electrodes are correctly connected and red if not. Three additional push buttons allow recalling a previously saved setting (Select Procedure), to assign a footswitch to a specific output socket (Footswitch), and to control several other functions (Menu), e.g. select language, touch tone control, output volume, or brightness. The touch screen is also used to show and modify the output settings (e.g. mode, output power, effect) as well as to control other functions (e.g. save settings). In addition, the proposed ESG-200 has a bipolar socket (with automatic instrument recognition of selected Olympus instruments), a monopolar socket (E- or B-Type depending on the model), and a neutral electrode socket.Indications for Use

Intended Use

Olympus ESG-200 Electrosurgical Generators intended for tissue cutting and coagulation in conjunction with electrosurgical accessories and ancillary equipment.

Technological Characteristics

The ESG-200 generator has the same intended use and technological characteristics as the primary predicate ESG-400 device. Various instruments can be connected to the monopolar and bipolar sockets. In addition, dedicated Olympus instruments can be connected to the bipolar socket with integrated self-recognition.
The PK modes of the primary predicate device (K141225) are not integrated in the ESG-200. The basic design philosophy of the User Interface (UI) and GUI flow chart concept is identical, except for the special ESG-400 amendment in regards to the PK instruments.

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

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

Subject ESG-200 Model "CELON PRECISION"	**Subject ESG-200 Model "CELON ELITE"**	**Predicate ESG-400**
FineCut	FineCut	FineCut (Effect 1)
PureCut	PureCut	PureCut (Effect 2)
StrongCut	StrongCut	PureCut (Effect 3)
N/A	PulseCut	PulseCut slow (Effect 2)

N/A	N/A	Blend Cut
N/A	N/A	PulseCut fast

Monopolar Cut Modes

Subject ESG-200Model "CELON PRECISION"	**Subject ESG-200Model "CELON ELITE"**	**Predicate ESG-400**
SoftCoag	SoftCoag	SoftCoag (Effect 3)
ForcedCoag	ForcedCoag	ForcedCoag (Effect 3)
N/A	N/A	PowerCoag
N/A	N/A	SprayCoag

Monopolar Coagulation Modes

Subject ESG-200 Model "CELON PRECISION"	**Subject ESG-200 Model "CELON ELITE"**	**Predicate ESG-400**
FineCut	FineCut	BipolarCut (Effect 1)
PureCut	PureCut	BipolarCut (Effect 2)
StrongCut	StrongCut	BipolarCut (Effect 3)
N/A	N/A	SalineCut
N/A	N/A	PK PureCut
N/A	N/A	PK SoftCut
N/A	N/A	PK LoopCut
N/A	N/A	PK MorceCut

Bipolar Cut Modes

Subject ESG-200 Model "CELON PRECISION"	**Subject ESG-200 Model "CELON ELITE"**	**Predicate ESG-400**
SoftCoag	SoftCoag	BiSoftCoag (Effect 3)
N/A	Strong RFITT	RFCoag (w/o RCAP)
N/A	Strong RFITT + RCAP	RFCoag (w/ RCAP)
N/A	N/A	AutoCoag
N/A	N/A	SalineCoag
N/A	N/A	HardCoag
N/A	N/A	FineCoag
N/A	N/A	PK Coag
N/A	N/A	PK Softcoag
N/A	N/A	PK AutoCoag

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.

RFITT output modes in comparison to the secondary predicate devices
Additional bipolar coagulation modes were implemented exclusively for the RFITT (radiofrequency induced thermotherapy) functionality in conjunction with dedicated Olympus bipolar applicators.

Subject ESG-200 Model "CELON PRECISION"	**Secondary predicate VNUS Radiofrequency Generator, Model RFG2 (K040638)**
RFITT	only RF power available (no further modes)
Pulse RFITT	
Power RFITT	

CELON PRECISION RFITT - Bipolar Coagulation Modes

Subject ESG-200 Model "CELON ELITE"	**Secondary predicate Celon Lab ENT (K032838)**
Fine RFITT	RFITT mode (no further modes)
Pure RFITT	

CELON ELITE RFITT - Bipolar Coagulation Modes

Substantial Equivalence

Substantial equivalence is demonstrated by acknowledged verification/validation methodologies. The subject devices have equivalent technology, performance, dimensions and materials. The differences to the primary predicate 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
- RFITT - Radiofrequency induced thermotherapy in conjunction with dedicated Olympus instruments

Regarding the additionally implemented bipolar coagulation modes, exclusively for RFITT (radiofrequency induced thermotherapy) functionality, two secondary predicate devices were chosen because of their specific output modes. Substantial equivalence has been demonstrated by acknowledged verification/validation methodologies. The subject devices have equivalent technology and performance in respect to the compared modes.

Performance Data

The following performance data were provided in support of the substantial equivalence determination. All standards applied were FDA recognized international standards. 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 “Moderate Level of Concern”.

Performance Testing - Bench

In general, the evaluations compared the function of the ESG-200 against the performance characteristics defined by the Design Specification and in comparison to the performance characteristics of the predicate devices. To demonstrate substantial equivalence the following aspects were considered within the validation versus the predicate devices. The results demonstrate that comparable tissue effects and electrical waveforms are achieved with subject and predicate devices for all modes of operation.

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 devices.

The purpose of the bench validation testing was to show equivalence of the electrical waveform between the subject and predicate devices. Appendices in section 12 detail the validation testing. An oscilloscope and high voltage probe were used as measuring and test equipment. The electrical waveforms of the ESG-200 were in all cases comparable to the electrical waveforms of the predicate. This was confirmed for all output modes (waveforms) at rated load.

Porcine muscle, kidney and liver tissue were used to demonstrated tissue effect equivalence between subject and predicate devices (Appendix 12b). Waveform Validation reports for ESG-200 at all outputs and and at rated load are provided in Appendix 12c

Comprehensive validation bench tests demonstrated and confirmed substantial equivalence to the predicate devices. Testing confirmed that comparable tissue effects and electrical waveforms could be achieved for all modes of operation. Clinical and animal studies were not deemed necessary to support substantial equivalence.

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)	19-5 07/09/2014
IEC 60601-1-2 Ed. 3.0 b:2007	Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests	19-1 10/17/2014
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
IEC 60601-2-2 Ed. 5.0: 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 [Including: Technical Corrigendum 1 (2014)]	6-336 01/27/2015
IEC 62304 Ed. 1.0 b: 2006	Medical device software - Software life cycle processes	13-8 08/20/2012
IEC 60601-1-6 Ed. 3.0: 2010	Medical electrical equipment Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability	5-85 07/09/2014
ISO 14971Second edition 2007	Medical devices - Application of risk management to medical devices	5-40 08/20/2012

Conclusion

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

In summary, we believe the ESG-200 is substantially equivalent with the predicate devices with respect to the general design approach, function, and the intended use. The ESG-200 raises no new concerns of safety or effectiveness when compared to the predicate devices.