April 28, 2021

Olympus Winter & Ibe GmbH
% Christina Flores
Regulatory Affairs Manager
Olympus Surgical Technologies America
118 Turnpike Road
Southborough, Massachusetts 01772

Re: K203277
Trade/Device Name: Electrosurgical Generator ESG-410, Foot Switches, PK Cutting Forceps
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical Cutting and Coagulation Device and Accessories
Regulatory Class: Class II
Product Code: GEI
Dated: March 29, 2021
Received: March 30, 2021

Dear Christina Flores:

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,

Long Chen, 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*

K203277

Device Name
Electrosurgical Generator ESG-410 and Accessories

Indications for Use *(Describe)*

ESG-410:

The electrosurgical generator, in conjunction with electrosurgical accessories and ancillary equipment, is intended for cutting and coagulation of tissue in the following medical fields:

- Open surgery
- Laparoscopic 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.

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

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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)*

K203277

Device Name
PK Cutting Forceps (CF-PK0533)

Indications for Use *(Describe)*
The PK Cutting Forceps are indicated for electrosurgical coagulation, mechanical cutting, and grasping of tissue during the performance of laparoscopic and open general surgical procedures.

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.

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2 510(k) Summary of Safety and Effectiveness

2.1 General Information

Applicant is:
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Kuehnstrasse 61
22045 Hamburg
Germany
Establishment Registration Number: 9610773

Manufacturer:
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14513 Teltow
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Establishment Registration Number: 3003724334

Contract Manufacturer:
STEUTE TECHNOLOGIES GMBH & CO. KG
Brueckenstrasse 91
32584 Loehne Nordrhein-Westfalen
Germany
Establishment Registration Number: 3015515531

510(k) Correspondent:
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Manager, Regulatory Affairs
Olympus Surgical Technologies America
118 Turnpike Road
Southborough, MA 01772
Phone: 508-808-3341
Email: christina.flores@olympus.com

Establishment Registration Number: 3003790304

Date prepared: November 5, 2020

2.2 Device Identification

Device name and models: Electrosurgical Generator ESG-410 and Accessories, and PK Cutting Forceps (PK-CF0553)

Common name: Electrosurgical Generator and Accessories, Electrosurgical devices

Classification Number:	21 CFR 878.4400
Classification name:	Electrosurgical cutting and coagulation device and accessories
Product code:	GEI
Product code name:	Electrosurgical, Cutting & Coagulation Accessories
Regulatory class:	Class II
Review Panel:	General & Plastic Surgery

2.3 Predicate Device

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

Predicate Device	Manufacturer	510(k) No
ESG-400	Olympus Winter & Ibe GmbH	K141225
PK Cutting Forceps	Olympus Surgical Technologies America	K142759

Table 2.1: Identification of predicate device

The following reference devices for the ESG-410 for particular monopolar and/or bipolar cutting and/or coagulation modes only have been chosen for substantial equivalence discussion in terms of safety and effectiveness.

Reference devices	Manufacturer	510(k) No
Valleylab™ FT10 Energy Platform	Covidien	K151649
VIO ESU (Model VIO 300D)	Erbe USA, Inc.	K060484

Table 2.2: Reference devices for a few specific features

2.4 Product Description

ESG-410 Generator

The subject device ESG-410 is a reusable, non-sterile electrosurgical generator that features different mono- and bipolar cutting and coagulation modes. The maximum output power is 320 W.

The front panel of the proposed ESG-410 features a touch screen GUI (graphical user interface) that displays the connection status of accessories and peripherals connected to the electrosurgical generator.

The front panel of the proposed ESG-410 features a touch screen GUI (graphical user interface) that 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 assess user-defined settings and procedures.

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

PK Cutting Forceps
The PK Cutting Forceps are a bipolar electrosurgical device that may be utilized in laparoscopic and open general surgery to grasp, coagulate, transect, dissect and retract tissue. The PK Cutting Forceps were cleared via K142759. They are currently intended to be used only with the existing ESG-400 generator per the Indications for Use statement. This submission will demonstrate compatibility with the new ESG-410 generator, and the Indications for Use statement will remove a specific generator model and the compatible generators will be reflected in the labeling. Minor modifications, which did not affect safety and effectiveness, were assessed via internal documentation since the original clearance and will be identified within the submission.

2.5 Indications for Use

ESG-410 Electrosurgical Generator
The electrosurgical generator, in conjunction with electrosurgical accessories and ancillary equipment, is intended for cutting and coagulation of tissue in the following medical fields:

- Open surgery
- Laparoscopic surgery
- Endoscopic surgery

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

PK Cutting Forceps
The PK Cutting Forceps are indicated for electrosurgical coagulation, mechanical cutting, and grasping of tissue during the performance of laparoscopic and open surgical procedures.

2.6 Technological Characteristics

The subject ESG-410 has the same intended use and technological characteristics as the predicate device ESG-400.
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 ESG-400, the ESG-410 offers additional output modes.

There have been no changes to the intended use or technological characteristics of the PK Cutting Forceps, since its clearance in K142759.

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

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

Subject Device: ESG-410	**Predicate Device: ESG-400** (K141225)
PureCut	PureCut
BlendCut	BlendCut
PulseCut Fast	PulseCut Fast
PulseCut Slow	PulseCut Slow
FineCut	FineCut
PowerCut	PowerCoag

Table 2.3: Monopolar Cut Modes

Subject Device: ESG-410	**Predicate Device: ESG-400** (K141225)
Spray	SprayCoag (Effect 3)
SprayCoag	SprayCoag
PowerCoag	PowerCoag
ForcedCoag	ForcedCoag

Table 2.4: Monopolar Coagulation Modes

Subject Device: ESG-410	**Predicate Device: ESG-400** (K141225)
BipolarCut	BipolarCut
PlasmaCut	SalineCut
PK LoopCut	PK LoopCut
PK MorceCut	PK MorceCut
PK PureCut	PK PureCut
PK SoftCut	PK SoftCut

Table 2.5: Bipolar Cut Modes

Subject Device: ESG-410	**Predicate Device: ESG-400** (K141225)
BiSoftCoag	BiSoftCoag
AutoCoag	AutoCoag
HardCoag	HardCoag
SalineCoag	SalineCoag
PK SoftCoag	PK SoftCoag
PK Coag	PK Coag
N/A	RFCoag (w/o RCAP)
N/A	RFCoag (w/ RCAP)

Subject Device: **ESG-410**	**Predicate Device:** **ESG-400** (K141225)
N/A	FineCoag
N/A	PK AutoCoag

Table 2.6: Bipolar Coagulation Modes

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

2.6.2 Output modes in comparison to the reference devices

As stated above, the reference devices are solely used for specific additional monopolar tissue cutting and coagulation modes that are comparable in the subject device and reference device.

2.6.2.1 COVIDIEN ValleylabTM FT10 Energy Platform

The reference device COVIDIEN Valleylab™ FT10 Energy Platform is provided for implementation of monopolar cutting and for monopolar coagulation modes that are not presented in the predicate device, the ESG-400.

Subject Device: **ESG-410**	**Reference Device** **COVIDIEN Valleylab™ FT10 Energy Platform** (K151649)
Pure	Pure
Blend	Blend

Table 2.7: Monopolar Cut Modes – Reference Device - COVIDIEN Valleylab™ FT10 Energy Platform

Subject Device: **ESG-410**	**Reference Device** **COVIDIEN Valleylab™ FT10 Energy Platform** (K151649)
Fulgurate	Fulgurate

Table 2.8: Monopolar Coagulation Modes – Reference Device – COVIDIEN Valleylab™ FT10 Energy Platform

The range of output waveforms and the power levels are equivalent in comparison to the FDA cleared COVIDIEN ValleylabTM FT10 Energy Platform, K151649.

2.6.2.2 ERBE VIO ESU (Model VIO 300D)

The reference device ERBE VIO ESU (Model VIO 300D) is provided for implementation of the monopolar coagulation mode SoftCoag, that is not presented in the predicate device, the ESG-400.

Subject Device: **ESG-410**	**Reference Device** **ERBE VIO ESU (Model VIO 300D)** (K060484)
SoftCoag	Soft Coag

Table 2.9: Monopolar Coagulation Mode – Reference Device – ERBE VIO ESU (Model VIO 300D)

The range of output waveforms and the power levels are equivalent in comparison to the FDA cleared ERBE VIO ESU (Model VIO 300D), K060484.

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 to the predicate device ESG-400 are:

- Two identical monopolar output sockets in the ESG-410, compared to two various monopolar (E-type and B-type) output sockets in the predicate device
- Two universal output sockets in the ESG-410, compared to one universal output socket in the predicate device
- no docking station interface on the bottom in the ESG-410
- Three foot switch sockets, all suitable for double pedal wired and wireless and for single pedal wired in the ESG-410, compared to two foot switch socket, both suitable for double pedal and single pedal
- The CQM indicator is integrated into the touch screen of the ESG-410, in the predicate device the CQM indicator is placed below the lower monopolar output socket
- The touch screen of the ESG-410 is approximately one third larger compared to the size of the predicate device.
- Three soft buttons for 'Settings', 'Procedure', 'Foot switch' and one Info button for the 'CQM' are integrated in the home screen of the ESG-410 compared to three buttons that were integrated into the touch screen of the predicate device
- The ESG-410 has one additional ventilation slot on the rear panel.
- The ESG-410 provides 28 ventilation slots on the side panels, compared to 32 ventilation slots provided by the predicate device
- The ESG-410 provides an USB-socket for storage, import and export of user-defined procedures on a portable USB flash drive. The USB-socket is not provided in the ESG-400

Regarding the additionally implemented monopolar cutting and coagulation modes two reference devices have been chosen, because of their specific output modes. For those two reference devices, the substantial equivalence is demonstrated by acknowledged verification/ validation methodologies. The subject devices have equivalent technology and performance in respect to the compared modes.

The previously cleared PK Cutting Forceps (K142759) are included in this submission to demonstrate compatibility with the subject ESG-410 generator and to update the labeling. There have been no changes to the technological characteristics or intended use of the device since its original clearance. The basic compatibility testing and limited electrical testing demonstrate substantial equivalence to the originally cleared PK Cutting Forceps.

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 its accessories do not contain components that come directly or indirectly in patient contact. Biocompatibility testing according to ISO 10993 is not required.

Biocompatibility evaluation of the previously cleared PK Cutting Forceps (PK-CF0533) was successfully established in K142759 according to ISO 10993-1 Biological Evaluation of Medical Devices-Part 1: Evaluation and Testing. There have been no changes to the device that affect the biocompatibility established in K142759.

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

There have been no changes to the PK Cutting Forceps since the original clearance that affect electrical safety or electromagnetic compatibility. However, "ACTIVE ACCESSORY HF Dielectric Strength" testing per IEC 60601-2-2:2017 Ed.6, Clause 201.8.8.3.103 and "Maximum Temperature During Normal Use" testing per IEC 60601-2-2:2017 Ed.6, Clause 201.11.1.1 were repeated for the PK Cutting Forceps with the ESG-410 generator. This testing was part of the basic compatibility testing to demonstrate compatibility of the PK Cutting Forceps with the subject ESG-410 generator.

2.8.3 Thermal Safety

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

2.8.4 Clinical and animal Studies

Clinical and animal studies were not necessary.

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".

The previously cleared PK Cutting Forceps (K147259) do not contain software.

2.8.6 Performance Testing Bench

ESG-410 Electrosurgical Generator

To demonstrate substantial equivalence 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 tissue effects were compared directly between the subjected and predicate device and between the subject and reference 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.

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. The tissue effects testing included quantitative and qualitative assessment.

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.

PK Cutting Forceps (PK-CF0533)
Basic compatibility testing was conducted to confirm compatibility of the legacy PK Cutting Forceps with the subject ESG-410 generator. "ACTIVE ACCESSORY HF Dielectric Strength" testing per IEC 60601-2-2:2017 Ed.6, Clause 201.8.8.3.103 and "Maximum Temperature During Normal Use" testing per IEC 60601-2-2:2017 Ed.6, Clause 201.11.1.1 were repeated for the PK Cutting Forceps with the ESG-410 generator as part of the basic compatibility testing to demonstrate compatibility with the new generator.

2.8.7 Reprocessing

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

The PK Cutting Forceps are provided sterile, for single-use. They are not intended to be reprocessed.

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 Ed. 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 09/17/2018
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 08/06/2013
IEC 60601-2-2 Ed. 6.0: 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 08/21/2017
IEC 62304 Ed. 1.1 2015 consolidated version	Medical device software - Software life cycle processes	13-79 01/14/2019
IEC 60601-1-6 Ed. 3.1: 2013	Medical electrical equipment Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability	5-89 06/27/2016
IEC 62366-1 Edition 1.0 2015	Medical devices – Part 1: Application of usability engineering to medical devices [Including CORRIGENDUM 1 (2016)]	5-114 12/23/2016
ISO 14971 second edition 2007	Medical devices – Application of risk management to medical devices	5-40 06/27/2016

Table 2.10: 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 subject ESG-410 and the compatibility of the PK Cutting Forceps with the subject ESG-410, raise no new concerns of safety or effectiveness when compared to the predicate and the reference devices.