



May 17, 2021

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

Re: K203682

Trade/Device Name: Electrosurgical Generator ESG-400 and Accessories,
POWERSEAL Curved Jaw Sealer and Divider, Double Action (PS-0523CJDA,
PS-0537CJDA, PS-0544CJDA).

Regulation Number: 21 CFR 878.4400

Regulation Name: Electrosurgical Cutting and Coagulation Device and Accessories

Regulatory Class: Class II

Product Code: GEI

Dated: December 16, 2020

Received: December 17, 2020

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

Indications for Use

510(k) Number (if known)

K203682

Device Name

Electrosurgical Generator ESG-400 and Accessories

Indications for Use (Describe)

The ESG-400 is an electrosurgical generator intended for tissue cutting and coagulation in open, laparoscopic and endoscopic surgery 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.

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Indications for Use

510(k) Number (if known)

K203682

Device Name

POWERSEAL Curved Jaw Sealer and Divider, Double Action (PS-0523CJDA, PS-0537CJDA, PS-0544CJDA)

Indications for Use (Describe)

The POWERSEAL Sealer and Divider is a bipolar electrosurgical device intended for use in laparoscopic/minimally invasive or open surgical procedures where ligation and division of vessels, tissue bundles, and lymphatics is desired. POWERSEAL devices can be used on vessels (arteries and veins, pulmonary arteries, pulmonary veins) up to and including 7 mm, lymphatics, and tissue bundles. POWERSEAL devices are indicated for use in general surgery and such surgical specialties as urologic, colorectal, bariatric, vascular, thoracic, and gynecologic. Procedures may include, but are not limited to, Nissen fundoplication, colectomy, cholecystectomy, adhesiolysis, sleeve gastrectomy, hysterectomy, oophorectomy.

The POWERSEAL Sealer and Divider has not been shown to be effective for tubal sterilization or tubal coagulation for sterilization procedures. Do not use the POWERSEAL devices for these 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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510(k) Summary of Safety and Effectiveness

Date Prepared: December 16, 2020

General Information

Manufacturer

(ESG-400 Generator): Olympus Winter & Ibe GmbH
Kuehnstr. 61
22045 Hamburg Germany

Establishment Registration Number: 9610773

Manufacturer (POWERSEAL Sealer and Divider) Olympus Surgical Technologies America
9600 Louisiana Ave. North
Brooklyn Park, MN 55455
USA

Establishment Registration Number: 3011050570

Official Correspondent: Christina Flores, RAC
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Establishment Registration Number: 3003790304

Device Identification

Proprietary names: Electrosurgical Generator ESG-400
POWERSEAL Curved Jaw Sealer and Divider,
Double Action (PS-0523CJDA, PS-0537CJDA, PS-0544CJDA)

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
 Generic/Common Name: Electrosurgical, Cutting & Coagulation & Accessories

Predicate Device

ESG-400 Generator

The initial version of the proposed medical device ESG-400 was cleared by the FDA in 2011 (K103032). This submission is based on a modification of the initial device version ESG-400 cleared by the FDA in 2014 (K141225). The 2014 clearance is the latest clearance for the device to date. The subject device ESG-400 therefore is a modification of the already legally marketed predicate electrosurgical generator ESG400 (K141225).

Predicate Device	Manufacturer	510(k) No
ESG-400	Olympus Winter & Ibe GmbH	K141225

Table 1: Identification of predicate device

This submission has been triggered by the development of new compatible POWERSEAL instruments, and the subsequent required software update of the generator.

The ESG-400 software update extends the instrument portfolio which can be driven by the ESG-400. It adds a new coagulation mode to support the POWERSEAL technology to be used with sealing instruments for open and laparoscopic surgery.

The following reference device has been chosen to support the substantial equivalence claim in terms of safety and effectiveness for the bipolar vessel sealing mode “POWERSEAL” only.

Reference device	Manufacturer	510(k) No
Valleylab™ FT10 Electrosurgical Platform	Covidien	K151649

Table 2: Reference devices for one specific feature

POWERSEAL Sealer and Divider, Curved Jaw

The primary predicate device of the subject POWERSEAL Sealer/Divider is the Ligasure Maryland Jaw One-Step Sealer/Divider, Curved; and the reference predicate is the Ligasure Maryland Jaw Thoracic Sealer/Divider One-Step Sealing, Nano-Coated. The subject POWERSEAL shares the same fundamental technologies, including design, intended use, and principle of operation with both the predicate and reference device.

Predicate Device	Manufacturer	510(k) No
Ligasure Maryland Jaw One-Step Sealer/Divider, Curved	Covidien	K141153
Reference device	Manufacturer	510(k) No
Ligasure Maryland Jaw Thoracic Sealer/Divider One-Step Sealing, NanoCoated	Covidien	K181085

Product Description

ESG-400 Generator

The subject device ESG-400 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-400 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.

Push buttons are placed next to GUI to switch between the output sockets, to enter the Menu in order to edit settings/ procedures (e.g. save or delete a procedure), 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).

Compatible accessories, two footswitches a double-pedal footswitch, which is delivered with the generator and may also be ordered separately, and an optional singlepedal footswitch have been previously cleared (K141225) and are not impacted by the SW update described in this submission. Changes to the footswitches that have been made since original clearance are outlined below and discussed in Device Description and Specifications:

- Labeling Changes
- Improvement of bend relief
- Packaging change

POWERSEAL Sealer and Divider

The POWERSEAL 5mm laparoscopic curved jaw sealer divider is an electrosurgical bipolar device with an integral extending cutting blade. It features a pistol grip handle and will be provided in shaft lengths of 23, 37, and 44 cm.

The subject POWERSEAL devices will be provided as sterile, single-use, hand-held bipolar electrosurgical instruments designed for use with Olympus electrosurgical generators to ligate (seal) and divide (cut) vessels, tissue bundles, and lymphatics. Similar to the predicate LigaSure Maryland Jaw, the jaws of the POWERSEAL are designed to seal vessels, and grasp and dissect tissue during open and minimally invasive general surgical procedures using high frequency (HF) energy. A hand actuated mechanism allows the user to open and close the instrument jaws. When the instrument jaws are correctly placed over tissue or vessel to be sealed, the user operates a second control to initiate delivery of bipolar energy, which seals the tissue. When the sealing is complete, the user operates a separate control to activate a blade, which divides the tissue along the seal line.

The subject devices, ESG-400 and accessories and the POWERSEAL Sealer and Divider are class II medical devices under the regulation number 878.4400 and the product code GEI – “Electrosurgical cutting and coagulation device and accessories”. Regulation Medical Specialty: General & Plastic Surgery. They are compliant with FDA recognized consensus safety standards as listed in Table 11.

Indications for Use

ESG-400 Generator

The ESG-400 is an electrosurgical generator intended for tissue cutting and coagulation in open, laparoscopic and endoscopic surgery in conjunction with electrosurgical accessories and ancillary equipment.

POWERSEAL Sealer and Divider

The POWERSEAL Sealer and Divider is a bipolar electrosurgical device intended for use in laparoscopic/minimally invasive or open surgical procedures where ligation and division of vessels, tissue bundles, and lymphatics is desired. POWERSEAL devices can be used on vessels (arteries and veins, pulmonary arteries, pulmonary veins) up to and including 7 mm, lymphatics, and tissue bundles. POWERSEAL devices are indicated for use in general surgery and such surgical specialties as urologic, colorectal, bariatric, vascular, thoracic, and gynecologic. Procedures may include, but are not limited to, Nissen fundoplication, colectomy, cholecystectomy, adhesiolysis, sleeve gastrectomy, hysterectomy, oophorectomy.

The POWERSEAL Sealer and Divider has not been shown to be effective for tubal sterilization or tubal coagulation for sterilization procedures. Do not use the POWERSEAL devices for these procedures.

Technological Characteristics

ESG-400 Generator

The ESG-400 has the same intended use and technological characteristics as the predicate device ESG-400 (K141225).

Various instruments can be connected to various output sockets: two monopolar socket, one bipolar socket and one universal socket. In addition, dedicated Olympus instruments or Olympus cables can be connected to the universal socket with instrument recognition.

With respect to the predicate device ESG-400 (K141225) the basic design philosophy of the User Interface (UI) and GUI flow chart concept was not changed. User interface modifications were the result of implementing the new output mode to support the POWERSEAL technology as well as improvement of GUI usability derived from market surveillance. POWERSEAL technology related GUI changes have been implemented. They follow the general GUI flow chart concept of the ESG-400 referring to All/ Set/ Mode Screens.

Output modes in comparison to the predicate device ESG-400

In this chapter the different unchanged monopolar and bipolar cutting and coagulation modes of the subject and predicate device are listed:

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

Table 3: Monopolar Cut Modes

Subject Device: ESG-400	Predicate Device: ESG-400 (K141225)
SoftCoag	SoftCoag
ForcedCoag	ForcedCoag
SprayCoag	SprayCoag
PowerCoag	PowerCoag

Table 4: Monopolar Coagulation Modes

Subject Device: ESG-400	Predicate Device: ESG-400 (K141225)
BipolarCut	BipolarCut
SalineCut	SalineCut

Table 5: Bipolar Cut Modes

Subject Device: ESG-400	Predicate Device: ESG-400 (K141225)
BiSoftCoag	BiSoftCoag

AutoCoag	AutoCoag
Subject Device: ESG-400	Predicate Device: ESG-400 (K141225)
SalineCoag	SalineCoag
HardCoag	HardCoag
FineCoag	FineCoag
RFCoag (RCAP)	RFCoag (RCAP)

Table 6: Bipolar Coagulation Modes

Subject Device: ESG-400	Predicate Device: ESG-400 (K141225)
PK PureCut	PK PureCut
PK SoftCut	PK SoftCut
PK LoopCut	PK LoopCut
PK MorceCut	PK MorceCut

Table 7: Bipolar Plasmakinetic Cut Modes

Subject Device: ESG-400	Predicate Device: ESG-400 (K141225)
PK Coag	PK Coag
PK SoftCoag	PK SoftCoag
PK AutoCoag	PK AutoCoag

Table 8: Bipolar Plasmakinetic Coagulation Modes

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

Output modes in comparison to the reference device

As stated above, the reference device, Covidien Valleylab FT10 Electrosurgical Platform (K151649), is solely used for the newly implemented bipolar vessel sealing mode “POWERSEAL”, that is comparable in the subject device and in the reference device.

Subject Device: ESG-400	Reference Device COVIDIEN Valleylab™ FT10 Electrosurgical Platform (K151649)
SEAL	LigaSure

Table 9: Bipolar Coagulation Mode – Reference Device - COVIDIEN Valleylab™ FT10 Electrosurgical Platform

The range of output waveforms and the power levels of the POWERSEAL mode are comparable to the LigaSure mode of the FDA cleared COVIDIEN Valleylab™ FT10 Electrosurgical Platform, K151649.

POWERSEAL Sealer and Divider

The basic fundamental technology, including design, intended use, and principles of operation are the same between the subject and predicate Ligasure devices. Both the subject and predicate devices connect to a radiofrequency (RF) energy source. The Indications for Use statement is also similar but identifies additional surgical specialties that otherwise fall under the broader indications of the predicate devices. The following table outlines the similarities and differences between the subject and predicate devices.

K203682

**Electrosurgical Generator ESG-400 and Accessories
Olympus Winter & Ibe GmbH**

Traditional 510(k) Notification

Feature	Subject Device POWERSEAL Sealer and Divider	Predicate Device LigaSure Maryland Jaw Sealer/Divider (#K141153)	Reference Device Ligasure Maryland Jaw Thoracic Sealer/Divider One-Step Sealing, Nano- Coated (#K181085)
Indications for Use	<p>The POWERSEAL Sealer and Divider is a bipolar electrosurgical device intended for use in laparoscopic/minimally invasive or open surgical procedures where ligation and division of vessels, tissue bundles, and lymphatics is desired. POWERSEAL devices can be used on vessels (arteries and veins, pulmonary arteries, pulmonary veins) up to and including 7 mm, lymphatics, and tissue bundles. POWERSEAL devices are indicated for use in general surgery and such surgical specialties as urologic, colorectal, bariatric, vascular, thoracic, and gynecologic. Procedures may include, but are not limited to, Nissen fundoplication, colectomy, cholecystectomy, adhesiolysis, sleeve gastrectomy, hysterectomy, oophorectomy. The POWERSEAL Sealer and Divider has not been shown to be effective for tubal sterilization or tubal coagulation for sterilization procedures. Do not use the POWERSEAL devices for these procedures.</p>	<p>The LigaSure Sealer/Divider is a bipolar electrosurgical instrument intended for use in minimally invasive or open surgical procedures where ligation and division of vessels, tissue bundles, and lymphatics is desired. The LigaSure Sealer/Divider can be used on vessels (arteries and veins) up to and including 7 mm. It is indicated for use in general surgery and such surgical specialties as urologic, vascular, thoracic, and gynecologic. Procedures may include, but are not limited to, Nissen fundoplication, colectomy, cholecystectomy, adhesiolysis, hysterectomy, oophorectomy, etc. The LigaSure system has not been shown to be effective for tubal sterilization or tubal coagulation for sterilization procedures. Do not use the LigaSure system for these procedures.</p>	<p>The LigaSure Sealer/Divider is a bipolar electrosurgical instrument intended for use in minimally invasive or open surgical procedures where ligation and division of vessels, tissue bundles, and lymphatics is desired. The LigaSure Sealer/Divider can be used on vessels (arteries and veins, pulmonary arteries, pulmonary veins) up to and including 7 mm. It is indicated for use in general surgery and such surgical specialties as urologic, vascular, thoracic, and gynecologic. Procedures may include, but are not limited to, Nissen fundoplication, colectomy, cholecystectomy, adhesiolysis, hysterectomy, oophorectomy, etc. The LigaSure system has not been shown to be effective for tubal sterilization or tubal coagulation for sterilization procedures. Do not use the LigaSure system for these procedures.</p>
Design	Pistol Grip with Shaft and curved jaw	Pistol Grip with Shaft and curved jaw	Pistol Grip with Shaft and curved jaw
Size Range	5mm diameter in lengths of 23, 37, 44cm	5mm diameter in lengths of 23, 37, 44cm	5mm diameter in length of 30cm

K203682

Electrosurgical Generator ESG-400 and Accessories

Olympus Winter & Ibe GmbH

Output mode and name	Bipolar Sealing = POWERSEAL (Coag)	Bipolar Sealing = LigaSure (Coag)	Bipolar Sealing = LigaSure (Coag)
Sterility, single patient use, disposable	Yes	Yes	Yes

Table 10: Subject and Predicate comparison table

Substantial Equivalence

ESG-400 Generator

Substantial equivalence is demonstrated by acknowledged verification/validation methodologies. The subject device is a modified version of the predicate device ESG400 (K141225) and has equivalent technology, performance, dimensions and materials. The difference to the predicate device ESG-400 is:

- The newly implemented bipolar coagulation mode to support the POWERSEAL technology to be used with sealing instruments for open and laparoscopic surgery.

Regarding the additionally implemented bipolar coagulation mode “POWERSEAL”, one reference devices has been chosen, because of its specific output mode. For this reference devices the substantial equivalence is demonstrated by acknowledged verification/ validation methodologies. The reference device has equivalent technology and performance in respect to the compared mode.

POWERSEAL Sealer and Divider

In establishing substantial equivalence of the subject POWERSEAL Sealer and Divider to the predicate Ligasure Maryland devices, an evaluation of the indications for use, intended use and technological characteristics was conducted. The subject and predicate devices have similar technology, performance, dimensions and materials. Performance testing confirmed that the subject device is as safe and effective as the predicate device for the proposed indications for use.

Performance Testing

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

For the ESG-400 Generator, 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.

For the POWERSEAL Sealer and Divider, all data was prepared in accordance with the following FDA guidance documents: “*Premarket Notification (510(k)) Submissions for Bipolar Electrosurgical Vessel Sealers for General Surgery*” *Guidance for Industry and Food and Drug Administration Staff*, issued on August 15, 2016; and “*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 documents were followed for all relevant sections.

Biocompatibility testing**ESG-400 Generator**

The ESG-400 and its accessories do not contain components that come directly or indirectly in patient contact. Biocompatibility testing according to ISO 10993 is not required.

POWERSEAL Sealer and Divider

In accordance with ISO 10993-1 and the 2016 FDA guidance, *Use of International Standard ISO 10993-1, "Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process"*, the subject devices met all acceptance criteria for the following biocompatibility evaluations:

Cytotoxicity	ISO 10993-5:2009 Biological Evaluation of Medical Devices, Part 5: Tests for In Vitro Cytotoxicity
Material Mediate Pyrogen	ISO 10993-11:2017. Biological Evaluation of Medical Devices, Part 11: Tests for Systemic Toxicity.
ISO Acute Systemic Injection Test	ISO 10993-11: 2017 Biological Evaluation of Medical Devices Part 11: Tests for Systemic Toxicity.
ISO Intracutaneous Irritation Test	ISO 10993-10: 2010 Standard, Biological Evaluation of Medical Devices, Part 10: Tests for Irritation and Skin Sensitization.
ISO Guinea Pig Maximization Sensitization	ISO 10993-10:2010. Biological Evaluation of Medical Devices, Part 10: Tests for Irritation and Skin Sensitization.

Sterilization and Shelf Life Discussion**ESG-400 and accessories**

The ESG-400 generator and its accessories are not provide sterile. They are reusable devices.

POWERSEAL Sealer and Divider

Sterilization testing for the POWERSEAL Sealer and Divider was conducted in accordance with the FDA's Guidance for Industry and Food and Drug Administration Staff, "Submission and Review of Sterility Information in Premarket Notification (510(k)) Submissions for Devices Labeled as Sterile". Stability evaluation for the sterile packaging and for product performance supports the three year shelf life. Accelerated aging test was conducted as required per ISO 11607-1 and in accordance with ASTM F1980-16, the standard guide for accelerated aging of sterile barrier systems for medical devices.

Electrical safety and electromagnetic compatibility (EMC)

Basic safety and performance testing was performed in accordance with IEC standards. The design of the subject ESG-400 and footswitches and the subject POWERSEAL Sealer and Divider comply with recognized standards as listed in Table 11, respectively.

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

Thermal Safety

The design of the subject ESG-400 Generator and the subject POWERSEAL Sealer and Divider, comply with recognized standards as listed in Table 11.

Clinical and Animal Studies

Clinical studies were not necessary for the subject devices.

Animal Studies, including Acute and Chronic testing conducted demonstrate substantial equivalence of the subject POWERSEAL Sealer and Divider to the predicate device.

All data was prepared in accordance with the FDA guidance, “*Premarket Notification (510(k)) Submissions for Bipolar Electrosurgical Vessel Sealers for General Surgery*” Guidance for Industry and Food and Drug Administration Staff, issued on August 15, 2016; and “*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 documents were followed for all relevant sections.

Test	Contents
Chronic Animal Study	Chronic animal study was conducted on both the subject and predicate devices to demonstrate seal performance
Acute Animal Study	Acute animal study was conducted on both the subject and predicate devices to demonstrate seal performance and safety

Software

The software validation activities were performed for the subject ESG-400 Generator in accordance with the FDA Guidance, “Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices”, issued May 11, 2005. The device software is considered a “Major Level of Concern”.

The output modes of the subject device to the predicate device (K141225) have not been changed. Software regression tests confirmed that existing functionalities are not influenced and remain unaffected/ unchanged by the addition of the new coagulation mode. The electrical waveforms of these “predicate modes” have been verified.

The POWERSEAL Sealer and Divider does not contain software.

Performance Testing Bench

Verification and comparison bench studies were conducted to evaluate the functional performance of the newly implemented “POWERSEAL” mode. Ex-vivo Vessel Burst Pressure testing was conducted on both the subject and predicate devices to demonstrate vessel sealing performance.

Testing demonstrated that the performance requirements defined in the User Requirements Specification and Design Specification were met for both subject devices, and that they exhibit comparable performance characteristics to the predicate device and reference devices.

Bench testing results support the claim of substantial equivalence of the subject ESG400 and the subject POWERSEAL Sealer and Divider, to the predicate and reference devices.

The following non-clinical and preclinical tests were conducted:

- 1) non-clinical (electrical, mechanical, functional)
- 2) preclinical (simulated use) evaluation and testing of tissue effects and thermal safety and vessel burst pressure testing and vessel thermal margin

Usability and user interface were also assessed according to the risk management plan. 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.

Reprocessing

Required cleaning, disinfecting and drying procedures are described in the instructions for use for the ESG-400 Generator and accessories.

The POWERSEAL Sealer and Divider is provided sterile, for single-use. It is not intended to be reprocessed.

Applied standards

Standard No.	Standard Title	FDA-Recognition no + date	Applicability
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	-ESG-400 Generator -POWERSEAL Instrument
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	-ESG-400 Generator -POWERSEAL Instrument
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	-ESG-400 -POWERSEAL Instrument
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	-ESG-400 Generator -POWERSEAL Instrument
IEC 62304 Ed. 1.1 2015 consolidated version	Medical device software - Software life cycle processes	13-79 01/14/2019	-ESG-400
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	-ESG-400
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	-ESG-400 Generator -POWERSEAL Instrument
ISO 14971 second edition 2007/2019	Medical devices – Application of risk management to medical devices	5-40 06/27/2016	-ESG-400 Generator -POWERSEAL

			Instrument
ISO 11135: 2014	Sterilization of health care products - Ethylene oxide - Requirements for development, validation and routine control of a sterilization process for medical devices.	14-529 07/15/2019	-POWERSEAL Instrument
ISO 11607-1 Second edition 2019-02	Packaging for terminally sterilized medical devices - Part 1: Requirements for materials, sterile barrier systems and packaging systems	14-530 07/15/2019	-POWERSEAL Instrument
ASTM F1980-16	Standard Guide for Accelerated Aging of Sterile Barrier Systems for Medical Devices	14-497 12/23/2016	-POWERSEAL Instrument
ISO 10993-5: 2009	Biological Evaluation of Medical Devices, Part 5: Tests for In Vitro Cytotoxicity	2-245 12/23/2016	-POWERSEAL Instrument
Standard No.	Standard Title	FDA-Recognition no + date	Applicability
ISO 10993-10: 2010	Biological Evaluation of Medical Devices, Part 10: Tests for Irritation and Skin Sensitization	2-174 07/26/2016	-POWERSEAL Instrument
ISO 10993-11: Third edition 2017-09	Biological Evaluation of Medical Devices, Part 11: Tests for Systemic Toxicity	2-255 09/17/2018	-POWERSEAL Instrument
ISO 10993-7: Second edition 2008-10-15	Biological evaluation of medical devices - Part 7: Ethylene oxide sterilization residuals	14-408 01/30/2014	-POWERSEAL Instrument
ISO 10993-18:2020	Biological evaluation of medical devices — Part 18: Chemical characterization of medical device materials within a risk management process	2-276 07/06/2020	-POWERSEAL Instrument

Table 11: Applied standards

Conclusion

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

In summary, Olympus believes the ESG-400 Generator and accessories and the POWERSEAL Sealer and Divider are substantially equivalent to the predicate devices with respect to the general design approach, function, and the intended use. The subject ESG-400 Generator and the POWERSEAL Sealer and Divider raise no new concerns of safety or effectiveness when compared to the predicates and the reference devices.