September 27. 2021

Olympus Surgical Technologies America
Christina Flores
Manager, Regulatory Affairs
9600 Louisiana Blvd North
Brooklyn Park, Minnesota 55455

Re: K212643
Trade/Device Name: POWERSEAL Curved Jaw Sealer and Divider, Double Action
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical Cutting and Coagulation Device and Accessories
Regulatory Class: Class II
Product Code: GEI
Dated: August 18, 2021
Received: August 20, 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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*

K212643

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.

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

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510(k) Summary of Safety and Effectiveness
Gyrus ACMI, Inc.
POWERSEAL Curved Jaw Sealer and Divider, Double Action

Date Prepared: August 16, 2021

General Information

Manufacturer:
Gyrus ACMI, Inc.
9600 Louisiana Blvd. North
Brooklyn Park, MN 55455
USA

Establishment Registration Number: 3011050570

Contact Person:
Christina Flores
Manager, Regulatory Affairs

Device Description

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

Device Classification Name: Electrosurgical Cutting and Coagulation device and Accessories

Regulations number: 21 CFR 878.4400

Regulation Medical Specialty: General and Plastic Surgery

Regulatory Class: Class II

Product Code: GEI

Generic/Common Name: Electrosurgical Cutting and Coagulation device and Accessories

Predicate Devices

The POWERSEAL Curved Jaw Sealer and Divider, Double Action (PS-0523CJDA, PS-0537CJDA, and PS-0544CJDA) were cleared under K203682. This submission is

a modification to the device that intends to add compatibility with an Olympus generator, ESG-410 cleared under K203277.

The predicate device has not been subject to any recalls.

Product Description

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.

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 third control to activate a blade, which divides the tissue along the seal line.

The subject device, POWERSEAL Sealer and Divider is a 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.

The device is compliant with FDA recognized consensus safety standards as listed in **Appendix 13B.**

Technological Characteristics

The POWERSEAL Curved Jaw Sealer and Divider, Double Action (PS-0523CJDA, PS-0537CJDA, and PS-0544CJDA) is unchanged from the predicate device as cleared under K203682 in terms of intended use, design, performance, and technological characteristics. The only difference is in the labeling that identifies an additional compatible Olympus generator.

Material

The materials have not changed for these devices since their original clearance under K203682, in which full biocompatibility information was provided.

Indications for Use

The intended use of the modified device, as described in its labeling, has not changed as a result of the modification. The indications for use are as follows:

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. The 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.

Compliance to Voluntary Standards

The design of the POWERSEAL Curved Jaw Sealer and Divider, Double Action complies with the following standards:

Standards Number	Standard Title	FDA Recognition no + date	Testing Lab
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	Intertek, Fridely, MN, USA
IEC 60601-1-2 Ed. 4.0:2014-02	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	Intertek, Fridely, MN, USA
IEC 60601-2-2 Ed. 6.0:2017-03	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	Intertek, Fridely, MN, USA
IEC 62366-1 Ed. 1.0:2015-02	Medical devices – Part 1: Application of usability engineering to medical devices [Including CORRIGENDUM 1 (2016)]	5-114 12/23/2016	N/A
ISO 14971	Medical devices – Application of risk	5-40	N/A

Second Edition 2007-03-01	management to medical devices	06/27/2016	
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	N/A
ISO 11607-1 Second Edition 2019-2	Packaging for terminally sterilized medical devices - Part 1: Requirements for materials, sterile barrier systems and packaging systems	14-530 07/15/2019	N/A
ASTM F1980-16	Standard Guide for Accelerated Aging of Sterile Barrier Systems for Medical Devices	14-497 12/23/2016	N/A
ISO 10993-5:2009	Biological Evaluation of Medical Devices, Part 5: Tests for In Vitro Cytotoxicity	2-245 12/23/2016	WuXi AppTec in St. Paul, MN
ISO 10993-10:2010	Biological Evaluation of Medical Devices, Part 10: Tests for Irritation and Skin Sensitization	2-174 07/26/2016	WuXi AppTec in St. Paul, MN
ISO 10993-11 Third Edition 2019-09	Biological Evaluation of Medical Devices, Part 11: Tests for Systemic Toxicity	2-255 09/17/2018	WuXi AppTec in St. Paul, MN
ISO 10993-7 Second Edition 2008-10-15	Biological evaluation of medical devices - Part 7: Ethylene oxide sterilization residuals	14-408 01/30/2014	WuXi AppTec in St. Paul, MN
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	WuXi AppTec in St. Paul, MN

Summary of Sterilization and Shelf Life Discussion

The product and packaging materials as well as the sterilization mode has not changed since the original clearance in K203682, therefore no additional testing was needed.

Summary of Performance Testing

Non-clinical testing was conducted as part of demonstrating substantial equivalence to the predicate device and ensure that the performance criteria was met when used with the additional compatible generator. A risk analysis was completed to identify any new risks associated with the modification to the POWERSEAL Curved Jaw Sealer and Divider, Double Action. The following tests associated with the device modification were performed on the subject device according to the methods and acceptance criteria established in the original clearance K203682:

- Non-clinical (electrical, mechanical, functional)

- Preclinical (simulated use) evaluation and testing of tissue effects and thermal safety and vessel burst pressure testing and vessel thermal margin

Substantial Equivalence Discussion

The POWERSEAL Curved Jaw Sealer and Divider, Double Action has identical indications for use as the previously cleared POWERSEAL Curved Jaw Sealer and Divider, Double Action. There have been no changes in the device compared to the previously cleared device in K203682. The only difference is the compatibility with an additional cleared Olympus generator, ESG-410. The labeling has been updated to reflect this additional compatible generator.

Conclusion

In summary, the Gyrus ACMI POWERSEAL Curved Jaw Sealer and Divider, Double Action is substantially equivalent to the predicate devices and presents no new questions of safety or effectiveness.