October 25, 2023

Gyrus ACMI, Inc.
Dolan Mills
Program Manager, Regulatory Affairs
800 West Park Drive
Westborough, Massachusetts 01581

Re: K231327
Trade/Device Name: POWERSEAL Sealer and Divider
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical Cutting And Coagulation Device And Accessories
Regulatory Class: Class II
Product Code: GEI
Dated: September 21, 2023
Received: September 21, 2023

Dear Dolan 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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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: 2023.10.25 14:51:48 -04'00'

Mark Trumbore, Ph.D.
Assistant Director
DHT4A: Division of General Surgery Devices
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and Infection Control Devices
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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)*
K231327

Device Name
POWERSEAL Sealer and Divider
Model numbers: PS-0523CJSA, PS-0537CJSA, PS-0544CJSA, PS-0523SJDA, PS-0537SJDA, PS-0544SJDA

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.

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:

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"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."

K231327
510(k) Summary

General Information

Manufacturer:	Gyrus ACMI, Inc., an Olympus company 9600 Louisiana Ave. North Brooklyn Park, MN 55445 USA Phone: 1-763-416-3000
Establishment Registration Number:	3011050570
510(k) Submitter:	Gyrus ACMI, Inc. 800 West Park Dr. Westborough, MA 01581
Establishment Registration Number:	3003790304
Contact Person:	Dolan Mills Program Manager, Regulatory Affairs
Date Prepared:	May 8, 2023

Device Description

Classification Name:	Electrosurgical cutting and coagulation device and accessories
Regulatory Class	Class 2
Regulation Number	21 CFR 878.4400
Review Panel	General & Plastic Surgery
Product Code	GEI
Trade / Proprietary Name(s):	POWERSEAL Sealer and Divider
Generic/Common Name:	Electrosurgical, Cutting & Coagulation
Model Numbers:	PS-0523CJSA, PS-0537CJSA, PS-0544CJSA, PS-0523SJDA, PS-0537SJDA, PS-0544SJDA

Predicate Device

POWERSEAL	K212643, K203682

The predicate K212643 demonstrated POWERSEAL compatibility with the ESG-410 electrosurgical generator, with no other device changes as compared to its predicate, K203682. K203682 was the initial submission for POWERSEAL and included compatibility with the ESG-400 electrosurgical generator.

The predicate has not been subject to a design-related recall.

Device Description and Technological Characteristics

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

The 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 radiofrequency (RF) energy, otherwise known as 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 the 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 basic fundamental technology, including design, intended use, and principles of operation are the same between the subject and predicate devices. Both the subject and predicate devices connect to an RF energy source The Indications for Use statement is the same as the predicate device. The table below outlines the similarities and differences between the subject and predicate devices.

Intended Use / Indications

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.

Compliance to Standards

The following standards were used during the design and testing of the subject device:

Applied standards
IEC 60601-1:2005+AMD1:2012+AMD2:2020
IEC 60601-1-2 Edition 4.1: 2020
IEC 60601-2-2 Ed. 6.0: 2017
IEC 62366-1, Edition 1.0, 2015
ISO 14971: 2019
ISO 11135: 2014+A1:2018
ISO 11607-1: 2019
ASTM F1980-16: 2021
ISO 10993-5: 2009
ISO 10993-1:2018
ISO 10993-10: 2021
ISO 10993-11: 2017
ISO 10993-7: 2019
ISO 10993-18:2020

Summary of Performance Testing

Performance Testing Bench

For the subject device 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.

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

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

Bench testing results support the claim of substantial equivalence of the subject device to the predicate device.

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.

Electrical safety and EMC compatibility: Basic safety and performance testing was performed in accordance with IEC 60601-1, IEC 60601-1-2, and IEC 60601-2-2.

Mechanical and Functional: Verification and comparison bench studies were conducted to evaluate the mechanical and functional performance as compared to the predicate.

Stability: The subject devices have the same packaging and shelf-life as the predicate. Real time age testing will confirm the declared shelf-life.

Software: The POWERSEAL Sealer and Divider does not contain software.

Material

The composition of the subject device is nearly identical to the predicate device. Patient contacting materials are primarily plastics and stainless steel. Any differences in materials between the subject and predicate devices were subject to biocompatibility evaluation against ISO 10993.

Biocompatibility

The subject devices are classified in accordance with ISO 10993-1, as an External Communication Device, Tissue/Bone/Dentin, for limited exposure (<24 hours.).

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 meet all acceptance criteria for the following biocompatibility evaluations: Cytotoxicity, Material Mediated Pyrogen, ISO Acute Systemic Injection Toxicity, ISO Intracutaneous Irritation, and ISO Guinea Pig Maximization Sensitization.

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.

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

Performance testing demonstrated that the device is as safe, as effective, and performs as well as the predicate devices.

Sterilization

Sterilization for the subject device is the exact same as the predicate device.

Substantial Equivalence

In establishing substantial equivalence of the subject POWERSEAL Sealer and Divider to the predicate device, an evaluation of the indications for use, intended use and technological characteristics was conducted. The subject and predicate devices have the same 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.

Summary of differences and similarities between the subject and predicate devices		
Description	**Subject Device**	**Predicate Device (K212643/K203682)**
Intended Use	Exactly the same as the predicate	Same
Design	Pistol Grip with Shaft and curved jaw and straight jaw	Pistol Grip with Shaft and curved jaw
Prescription/over-the-counter use	Rx Only	Same
Size(s)	5mm diameter in lengths of 23, 37, 44cm	Same
Output mode and name	Bipolar Sealing = POWERSEAL (Coag)	Same
Sterile, single use, disposable	Yes	Same

Conclusion

The performance of the subject device was compared against performance requirements and the predicate listed above. Performance requirements were based on the predicate device and/or its predicate. Testing demonstrated that the performance requirements were met, and that the subject device exhibited comparable performance characteristics to the predicate. Any differences have

been validated and demonstrate that the technological differences do not raise different questions of safety and efficacy.

In summary, the Gyrus ACMI POWERSEAL Sealer and Divider is substantially equivalent to the predicate device and does not raise different questions of safety and effectiveness.