March 2, 2026

Gyrus ACMI, Inc
Apurva Joshi
Regulatory Affairs Specialist II
800 West Park Drive
Westborough, Massachusetts 01581

Re: K252487
Trade/Device Name: POWERSEAL Open Extended Jaw Sealer and Divider, Double-Action (PS-0021EJDA)
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical Cutting And Coagulation Device And Accessories
Regulatory Class: Class II
Product Code: GEI
Dated: February 4, 2026
Received: February 4, 2026

Dear Apurva Joshi:

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 Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13484 clause 8.3 (Nonconforming product), and ISO 13485 clause 8.5 (Corrective and preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 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 Management System Regulation (QMSR) (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.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

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,

Colin K. Chen -S

Digitally signed by Colin K. Chen -S
Date: 2026.03.02 22:41:35 -05'00'

Colin K. Chen, Ph.D.
Acting 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

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.	K252487

Please provide the device trade name(s).

POWERSEAL Open Extended Jaw Sealer and Divider, Double-Action (PS-0021EJDA)

Please provide your Indications for Use below.

The POWERSEAL Open Extended Jaw, Sealer & Divider, Double- Action is a bipolar electrosurgical instrument intended for use in open surgical procedures where ligation and division of vessels, tissue bundles, and lymphatics is desired.
POWERSEAL Open Extended Jaw, Sealer & Divider, Double-Action instruments can be used on vessels (arteries, veins, pulmonary arteries, pulmonary veins) up to and including 7 mm.
POWERSEAL Open Extended Jaw, Sealer & Divider, Double-Action instruments are indicated for use in general surgery and such surgical specialties as urologic, colorectal, vascular, thoracic, and gynecologic. Procedures may include, but are not limited to Nissen fundoplication, colectomy, cholecystectomy, adhesiolysis, hysterectomy, and oophorectomy.
The POWERSEAL Open Extended Jaw has not been shown to be effective for tubal sterilization or tubal coagulation for sterilization procedures. Do not use POWERSEAL Open Extended Jaw for these procedures.

Please select the types of uses (select one or both, as applicable).

- ☒ Prescription Use (Part 21 CFR 801 Subpart D)
- ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

K252487 510(k) Summary

POWERSEAL Open Extended Jaw Sealer and Divider (PSOEJ)

I. Submitter

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:	Apurva Joshi Regulatory Affairs Specialist II Phone: 1-617-512-5935 Email: apurva.joshi@olympus.com
Alternate Contact:	Dolan Mills Sr. Program Manager, Regulatory Affairs Phone: 1-901-355-0007 Email: dolan.mills@olympus.com
Date Prepared:	March 2, 2026

II. Device Description

Trade Name:	POWERSEAL Open Extended Jaw Sealer and Divider
Model Number:	PS-0021EJDA
Generic/Common Name:	Electrosurgical, Cutting & Coagulation
Classification Name:	Electrosurgical cutting and coagulation device and accessories
Regulation/CFR Citation Number:	21 CFR 878.4400
Product Code:	GEI
Classification:	Class II
Review Panel:	General & Plastic Surgery

III. Predicate Device

LigaSure Impact LF4418	K162047

The predicate has not been subject to a recall.

Device Description and Technological Characteristics

The POWERSEAL Open Extended Jaw, Sealer & Divider, Double-Action is a bipolar electrosurgical instrument intended for use in open surgical procedures where ligation and division of vessels, tissue bundles, and lymphatics is desired. The subject device is referred to as PSOEJ in this submission.

The jaws of the PSOEJ are designed to work with an electrosurgical unit to seal vessels, and grasp and dissect tissue during open general surgical procedures using radiofrequency (RF) energy, also known as HF energy. A hand-actuated mechanism allows the user to open and close the instrument jaws. The device creates a seal by application of RF energy to vascular structures (vessels, lymphatics) or tissue bundles between the jaws of the device. When the sealing is complete, the user operates a separate control to activate a blade within the device, which divides the tissue along the seal line. The device is supplied sterile and is intended for single use.

The POWERSEAL Open Extended Jaw, Sealer and Divider, Double-Action is designed for use with Olympus electrosurgical generators, ESG-400 and ESG-410.

The PSOEJ model is specifically for open surgery and is a portfolio expansion to the existing POWERSEAL family (K231327, K212643).

The existing and proposed POWERSEAL devices share a similar handle interface designed to enhance usability and improve the surgeon’s ergonomic experience.

This device has demonstrated equivalent core clinical performance (strong sealing) via metrics such as vessel sealing indication (7mm), seal time, burst pressure, thermal margin and heat profile, and tissue sticking relative to the predicate LigaSure Impact (K162047).

Intended Use / Indications

The POWERSEAL Open Extended Jaw, Sealer & Divider, Double- Action is a bipolar electrosurgical instrument intended for use in open surgical procedures where ligation and division of vessels, tissue bundles, and lymphatics is desired.

POWERSEAL Open Extended Jaw, Sealer & Divider, Double-Action instruments can be used on vessels (arteries, veins, pulmonary arteries, pulmonary veins) up to and including 7 mm.

POWERSEAL Open Extended Jaw, Sealer & Divider, Double-Action instruments are indicated for use in general surgery and such surgical specialties as urologic, colorectal, vascular, thoracic, and gynecologic. Procedures may include, but are not limited to Nissen fundoplication, colectomy, cholecystectomy, adhesiolysis, hysterectomy, and oophorectomy.

The POWERSEAL Open Extended Jaw has not been shown to be effective for tubal sterilization or tubal coagulation for sterilization procedures. Do not use POWERSEAL Open Extended Jaw 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, AMD1:2020

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 10993-18:2020AMD1:2022

Summary of Performance Testing

Performance Testing Bench

For the subject PSOEJ 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 device, and that it exhibits 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 tests were conducted:

1) non-clinical (electrical, mechanical, functional), surgeon input design validation, bench burst pressure, and thermal effects testing.
2) non-clinical animal (simulated use) evaluation and testing of tissue effects and thermal safety and vessel burst pressure testing and vessel thermal margin

The acute and chronic studies performed on porcine and canine animal models adequately characterize vessel sealing performance and mitigate risks associated with ineffective sealing, unintended bleeding, excessive thermal injury, or unintended damage to adjacent or critical anatomical structures. The collective non-clinical testing data supports that the subject device performs comparably to the predicate and does not introduce new or increased risks to patient safety.

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 device has similar packaging and shelf-life as the predicate. Real time age testing will confirm the declared shelf-life.

Material

Patient contacting materials are primarily plastics and stainless steel. All the direct patient contacting materials of the device 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 PSOEJ 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 and effective as the predicate device.

Sterilization

The subject PSOEJ device is sterile single use device. The device is sterilized with Ethylene Oxide (EO) using the same sterilization process as the existing POWERSEAL family of devices.

Substantial Equivalence

In establishing substantial equivalence of the subject PSOEJ 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 and performance. Also, they are similar in 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	**Proposed POWERSEAL Open Extended Jaw (PSOEJ)**	**Predicate LigaSure Impact LF4418 cleared via K162047**	**Comparison comments**
Intended Use	Same as predicate	Same	Intended use is the Same. Indications are nearly identical, and the same in total.
Regulation	General & Plastic Surgery, 878.4400, GEI, class II	General & Plastic Surgery, 878.4400, GEI, class II	Same
Prescription/over-the-counter use	Rx Only	Rx Only	Same
Shaft length	21 cm	18 cm	Similar. PSOEJ is longer due to repositioned shaft rotation control – lengths are clinically equivalent
Primary mode of action	Bipolar electrosurgical device intended for ligation and division of vessels, tissue bundles, and lymphatics	Bipolar electrosurgical device intended for ligation and division of vessels, tissue bundles, and lymphatics	Same
Delivery	Sterile, single use	Sterile, single use	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 differences do not raise questions of safety and efficacy.

In summary, the subject POWERSEAL Open Extended Jaw Sealer and Divider is substantially equivalent to the predicate device and does not raise different questions of safety and effectiveness.