October 4, 2017

Olympus Medical Systems Corp.
% Graham Baillie
RA Manager
Gyrus ACMI, Inc.
136 Turnpike Road
Southborough, Massachusetts 01772

Re: K172691
Trade/Device Name: Ultrasonic Generator
Regulatory Class: Unclassified
Product Code: LFL, GEI
Dated: August 31, 2017
Received: September 6, 2017

Dear Graham Baillie:

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education (DICE) at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education (DICE) at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely,

Jennifer R. Stevenson -S3

For Binita S. Ashar, M.D., M.B.A., F.A.C.S.
Director
Division of Surgical Devices
Office of Device Evaluation
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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K172691

Device Name
Ultrasonic Generator USG-400

Indications for Use *(Describe)*

The Ultrasonic Generator (USG-400) is intended to be used with the Electrosurgical Generator (ESG-400), the THUNDERBEAT Transducer (TD-TB400), the SONICBEAT Transducer (TD-SB400), the THUNDERBEAT, and / or the SONICBEAT for open, laparoscopic (including single-site surgery), and endoscopic surgery to cut (dissect) or coagulate soft tissue or to ligate (seal and cut) vessels.

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:
Gyrus ACMI, Inc.
Ultrasonic Generator USG-400

General Information

Applicant:	OLYMPUS MEDICAL SYSTEMS CORP. 2951 Ishikawa-cho, Hachioji-shi, Tokyo, Japan 192-8507 Phone: (+81) 42-642-2694 Fax: (+81) 42-642-2307
Establishment Registration Number:	8010047
Manufacturer:	Aomori Olympus 248-1 Okkonoki 2-chome Kuroishi-shi, Aomori, Japan 036-0367 Phone: (+81) 172-52-8543 Fax: (+81) 172-52-8515
Establishment Registration Number:	9614641
510(k) Submitter:	Gyrus ACMI, Inc. 136 Turnpike Rd. Southborough, MA 01772-2104
Establishment Registration Number:	3003790304
Contact Person:	Graham A.L. Baillie MS Manager, Regulatory Affairs
Date Prepared:	August 31, 2017
Classification Name:	Endoscopic Electrosurgical unit and accessories
Regulation Number:	
Regulatory Class:	Unclassified
Product Codes:	LFL, GEI
Review Panel:	General & Plastic Surgery
Trade Name:	Ultrasonic Generator USG-400

Generic/Common Name: Ultrasonic Generator

Model Name	Device Name
USG-400	Ultrasonic Generator

Predicate Devices

Olympus Medical Systems Corp. Ultrasonic Generator USG-400 Ver 1 K111202

Device Description

The Ultrasonic Generator USG-400 Ver 2 is intended to be used with the Electrosurgical Generator ESG-400, the THUNDERBEAT Transducer TD-TB400, the SONICBEAT Transducer TD-SB400, the THUNDERBEAT hand instruments, and / or the SONICBEAT hand instruments.
It is an ultrasonic generator capable of vessel sealing & cutting, tissue coagulating & cutting, grasping, and dissecting.

Technological Characteristics

Output mode and Control
[Seal & Cut mode (THUNDERBEAT)]
The USG-400 Ver 2 communicates with the ESG-400 to control the HF Bipolar (FineCoag) output for the Seal & Cut mode. It also generates drive current for the Seal & Cut mode. The drive current is converted into the Ultrasonic output by the Transducer.

[Seal mode (THUNDERBEAT)]
The USG-400 Ver 2 communicates with the ESG-400 to control the HF Bipolar (HardCoag) output for the Seal mode.

[Ultrasonic (SONICBEAT)]
The USG-400 Ver 2 generates drive current for the ultrasonic output.

Intended Use

The Ultrasonic Generator (USG-400 Ver 2) is intended to be used with the Electrosurgical Generator (ESG-400), the THUNDERBEAT Transducer (TD-TB400), the SONICBEAT Transducer (TD-SB400), the THUNDERBEAT, and / or the SONICBEAT for open, laparoscopic (including single-site surgery), and endoscopic surgery to cut (dissect) or coagulate soft tissue or to ligate (seal and cut) vessels.

Comparison of Technological Characteristics

The proposed and predicate devices have similar technology, principles of operation, performance, dimensions and materials. A side-by-side comparison of the marketed and proposed devices is provided below.

Table 5.1 Comparison Table of Proposed and Predicate Devices

Feature	**Proposed** USG-400 Ver. 2	**Predicate** USG-400 (#K111202) Ver. 1
Manufacturer	Identical to PD	OLYMPUS MEDICAL SYSTEMS CORP.
Size: Width x Height x Depth	Identical to PD	375 ×156 ×480 mm
Weight	Identical to PD	9kg
Indications for Use	Identical to PD	The Ultrasonic Generator (USG-400) is intended to be used with the Electrosurgical Generator (ESG-400), the THUNDERBEAT Transducer (TD-TB400), the SONICBEAT Transducer (TD-SB400), the THUNDERBEAT, and / or the SONICBEAT for open, laparoscopic (including single-site surgery), and endoscopic surgery to cut (dissect) or coagulate soft tissue or to ligate (seal and cut) vessels.
Power supply: Rated voltage Rated frequency Input current	Identical to PD	120V AC / 220-240V AC 50 - 60 Hz 360 VA
Type of protection against electric shock	Identical to PD	Class 1
Degree of protection against electric shock	Identical to PD	CF
Display	Identical to PD	LCD (5.7inch, color)
Sockets for instruments	Identical to PD	Socket for THUNDERBEAT: 1 Socket for SONICBEAT: 1
Socket for Footswitch	Identical to PD	Footswitch for THUNDERBEAT: 1 Footswitch for SONICBEAT: 1
Output mode	Identical to PD	Ultrasonic output, Combined output (ultrasonic from

Feature	Proposed USG-400 Ver. 2	Predicate USG-400 (#K111202) Ver. 1
		USG-400 and RF bipolar from ESG-400 of K111202, K141225
Output level	Identical to PD	Ultrasonic output: Level 1 - Level 3 (by 1step) Combined output: Level 1 - Level 3 (by 1step) Output timing is controlled between Ultrasonic and RF Bipolar by level setting.
Ultrasonic Output Frequency	Identical to PD	47 kHz
Ultrasonic Output Voltage	Identical to PD	1000Vpp max
Ultrasonic Output Current	Identical to PD	0.57App
ITM (Intelligent Tissue Monitoring)	Equipped	Not equipped

Compliance to Voluntary Standards

The design of the proposed USG-400 Ver 2 complies with the following standards:

- IEC60601-1: 2005+A1 Medical electrical equipment – Part1: General Requirements for basic safety and essential performance
- IEC60601-1-2 Edition 3: 2007-03 Medical electrical equipment – Part 1-2; General requirements for basic safety and essential performance – Collateral Standard: Electromagnetic disturbances – Requirement and tests
- AAMI / ANSI / IEC 60601-2-2:2009, medical electrical equipment - part 2-2: particular requirements for the basic safety and essential performance of high frequency surgery equipment and high frequency surgical accessories.
- ISO14971 Second Edition: 2007-03-01 – Medical devices - Application of risk management to medical devices

Device-specific guidance

Premarket Notification (510(k)) Submissions for Bipolar Electrosurgical Vessel Sealers for General Surgery - Guidance for Industry and Food and Drug Administration Staff, 08/15/2016

Premarket Notification (510(k)) Submissions for Electrosurgical Devices for General Surgery - Guidance for Industry and Food and Drug Administration Staff, 08/15/2016.

Summary of Non-clinical Testing

Electrical safety and EMC performance testing have confirmed the subject USG-400 to be in compliance with relevant requirements.

Software testing has been performed and documented to be in compliance with the FDA guidance "ODE Guidance for the Contents of Premarket Submission for Software Contained in Medical Devices" issued on May 11, 2005.

Bench Testing:

Test Code	Item	Contents
#A	*Ex-vivo* Vessel Burst Pressure	*Ex-vivo* burst pressure testing of porcine blood vessels was conducted on both the subject and predicate devices to demonstrate vessel sealing performance.
#B	*Ex-vivo* Cutting Performance	*Ex-vivo* Cutting performance (Cutting time) testing of porcine mesentery was conducted on both the subject and predicate devices to demonstrate cutting performance.

Animal Testing: Porcine animal models were used for performance testing D.

Test Code	Item	Contents
#D	Acute Animal Study	Acute animal study of porcine was conducted on both the subject and predicate devices to demonstrate seal performance and safety (ex. seal maintenance rates include vessels up to 7.0mm in diameter and lymphatics and tissue bundles, thermal spread, degree of degeneration).

Software testing:

Test Code	Item	Contents
NA	Software	Software was classified as a "Major" Level of Concern according to guidance. Software testing and documentation supports this Level of Concern

Summary of Clinical Testing
Clinical testing using the proposed device was not conducted.

Conclusion:
Performance tests summarized above demonstrate that the proposed USG-400 Ver 2 is substantially equivalent to the predicate USG-400 Ver 1 and presents no new questions of safety or efficacy.