July 12, 2018

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

Re: K180575
Trade/Device Name: THUNDERBEAT 5 mm, 20 cm, Front-actuated Grip Type X,
THUNDERBEAT 5 mm, 35 cm, Front-actuated Grip Type X,
THUNDERBEAT 5 mm, 45 cm, Front-actuated Grip Type X

Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical cutting and coagulation device and accessories
Regulatory Class: II
Product Code: GEI, LFL
Dated: February 28, 2018
Received: March 5, 2018

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.

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 comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Binita S. Ashar -S

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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K180575

Device Name
THUNDERBEAT 5 mm, 20 cm, Front-actuated Grip Type X
THUNDERBEAT 5 mm, 35 cm, Front-actuated Grip Type X
THUNDERBEAT 5 mm, 45 cm, Front-actuated Grip Type X

Indications for Use *(Describe)*
The THUNDERBEAT hand instruments are intended to be used for open, laparoscopic, and endoscopic surgery to cut, seal, coagulate, grasp, and dissect.

Seal & Cut mode:
The THUNDERBEAT hand instruments when used in combination with the Seal & Cut mode are indicated for open, laparoscopic (including single-site surgery) general surgery and gynecological surgery (including urologic, thoracic, plastic and reconstructive, bowel resections, cholecystectomies, Nissen fundoplication, adhesiolysis, oophorectomy, hysterectomies (both vaginal assisted and abdominal) etc.), and endoscopic surgery or in any procedure in which cutting, vessel ligation (sealing and cutting), coagulation, grasping, and dissection is performed. These devices have been designed to seal and cut vessels (up to and including 7 mm in diameter), tissue bundles, and lymphatics.

Seal mode:
The THUNDERBEAT hand instruments when used in combination with the Seal mode are indicated for open, laparoscopic (including single-site surgery) general surgery and gynecological surgery (including urologic, thoracic, plastic and reconstructive, bowel resections, cholecystectomies, Nissen fundoplication, adhesiolysis, oophorectomy, hysterectomies (both vaginal assisted and abdominal) etc.), and endoscopic surgery or in any procedure in which vessel sealing, coagulation, grasping is performed. These devices have been designed to seal vessels (up to and including 7 mm in diameter), tissue bundles, and lymphatics.

The THUNDERBEAT hand instruments have not been shown to be effective for tubal sterilization or tubal coagulation for sterilization procedures, and should not be used 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.

510(k) Summary
Gyrus ACMI, Inc.
THUNDERBEAT Type X Hand Instruments

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 2-248-1 okkonoki kuroishi-shi aomori, Japan 036-0357 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:	February 28, 2018

Device Description

Classification Name:	Electrosurgical cutting and coagulation device and accessories
Regulation Number:	21 CFR 878.4400
Regulatory Class:	Class II,
Product Codes:	GEI, LFL
Review Panel:	General & Plastic Surgery

Trade Name: THUNDERBEAT Type X Hand Instruments

Model Name	Device Name
TB-0520FCX	THUNDERBEAT 5 mm, 20 cm, Front-actuated Grip Type X
TB-0535FCX	THUNDERBEAT 5 mm, 35 cm, Front-actuated Grip Type X
TB-0545FCX	THUNDERBEAT 5 mm, 45 cm, Front-actuated Grip Type X

Generic/Common Name: Ultrasonic and electrosurgical devices

Predicate Devices

Olympus Medical Systems Corp.
THUNDERBEAT TB-0520IC/0535PC/0545PC/0535IC/0545IC Hand Instruments
K132703

Product Description

The THUNDERBEAT Type X Hand Instruments are intended to be used with the Ultrasonic Generator (USG-400), the Electrosurgical Generator (ESG-400), and the THUNDERBEAT Transducer, (TD-TB400).

The THUNDERBEAT Type X Hand Instruments are provided as a sterile, single use devices. Type X devices are functional device capable of vessel sealing & cutting, tissue coagulating & cutting, grasping, and dissecting. These devices have been designed to seal and cut vessels up to and including 7 mm in diameter, tissue bundles, and lymphatics.

Comparison of Technological Characteristics

The THUNDERBEAT Type X Hand Instruments have the same intended use and fundamental scientific technological characteristics as the predicate THUNDERBEAT Hand Instruments cleared under K132703. The subject and predicate devices activate combined HF Bipolar (FineCoag) output and Ultrasonic output [Seal & Cut mode] simultaneously while grasping vessels, tissue bundles and lymphatics between the Probe and the Grasping section.

The THUNDERBEAT Type X Hand Instruments, like the predicate THUNDERBEAT, also activates the HF Bipolar (HardCoag) output [Seal mode]. Those outputs can be used for sealing and cutting/sealing of vessels, tissue bundles and lymphatics and or coagulating and cutting/coagulating tissues. The hand switches provided on the grip handle enable those output operations.

The differences between the THUNDERBEAT Type X and the predicate THUNDERBEAT include the following:

- Grasper shape difference in upper jaw
- Coating on underside of probe tip
- Addition of a cover to the outside of the electrode
- Front actuation grip on handle

Material

Full biocompatibility testing on all patient contacting surfaces has been performed in compliance to the relevant requirements of ISO-10993 series.

Indications for use

The THUNDERBEAT hand instruments are intended to be used for open, laparoscopic, and endoscopic surgery to cut, seal, coagulate, grasp, and dissect.

Seal & Cut mode:
The THUNDERBEAT hand instruments when used in combination with the Seal & Cut mode are indicated for open, laparoscopic (including single-site surgery) general surgery and gynecological surgery (including urologic, thoracic, plastic and reconstructive, bowel resections, cholecystectomies, Nissen fundoplication, adhesiolysis, oophorectomy, hysterectomies (both vaginal assisted and abdominal) etc.), and endoscopic surgery or in any procedure in which cutting, vessel ligation (sealing and cutting), coagulation, grasping, and dissection is performed. These devices have been designed to seal and cut vessels (up to and including 7 mm in diameter), tissue bundles, and lymphatics.

Seal mode:
The THUNDERBEAT hand instruments when used in combination with the Seal mode are indicated for open, laparoscopic (including single-site surgery) general surgery and gynecological surgery (including urologic, thoracic, plastic and reconstructive, bowel resections, cholecystectomies, Nissen fundoplication, adhesiolysis, oophorectomy, hysterectomies (both vaginal assisted and abdominal) etc.), and endoscopic surgery or in any procedure in which vessel sealing, coagulation, grasping is performed. These devices have been designed to seal vessels (up to and including 7 mm in diameter), tissue bundles, and lymphatics.

The THUNDERBEAT hand instruments have not been shown to be effective for tubal sterilization or tubal coagulation for sterilization procedures, and should not be used for these procedures.

Compliance to Voluntary Standards

The design of the THUNDERBEAT Type X Hand Instruments complies with the following standards:

IEC60601-1: 2005+A1:2012
IEC60601-1-2: 2001+A1, 2007
IEC60601-2-2:2009
IEC60601-2-18:2009
ISO10993-1:2009
ISO10993-5: 2009
ISO10993-7: 2008
ISO10993-10: 2010
ISO10993-11: 2006
ISO11135:2014
ISO14971:2007
ASTM F1980-16

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 Sterilization and Shelf Life Discussion

The sterilization has been tested to comply with ISO11135:2014.
The result of stability evaluation demonstrated that the THUNDERBEAT Type X has 3 years shelf-life performance.

Summary of Performance Testing

The following performance testing was conducted in support of the substantial equivalence determination.

1. 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.

Test Code	Item	Contents
#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.

2. Animal Test

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

3. Clinical Testing
Clinical testing was not performed.

Substantial Equivalence

The subject and predicate devices have the same fundamental technology and indications for use. The performance, dimensions and materials of the subject device are similar to those of the predicate. Compared to the predicate device (K132703), the subject device has a different shape in the Grasping section, a coating of insulating material has been added to the underside of the probe, and the handle is now a front-actuated grip. To support the proposed design modifications, the performance tests summarized above were conducted.

Conclusion:

In summary, the THUNDERBEAT Type X Hand Instruments are substantially equivalent to the predicate devices and present no new questions of safety or efficacy.