August 4, 2021

Olympus Medical Systems Corporation
% Anne-Marie Keefe
Program Manager
Olympus Surgical Technologies of America
800 West Park Drive
Westborough, Massachusetts 01581

Re: K211838
Trade/Device Name: Ultrasonic Bipolar Generator USG-410 with accessories
Regulatory Class: Unclassified
Product Code: LFL, GEI
Dated: June 11, 2021
Received: June 14, 2021

Dear Anne-Marie Keefe:

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

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K211838

Device Name
ULTRASONIC BIPOLAR GENERATOR USG-410 with accessories

Indications for Use *(Describe)*

1. ULTRASONIC BIPOLAR GENERATOR USG-410
The Electrosurgical & Ultrasonic Generator (USG-410) is intended to be used with the THUNDERBEAT Transducer, the SONICBEAT Transducer, the THUNDERBEAT 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.

2. THUNDERBEAT Open Extended Jaw TB-0920OE
The THUNDERBEAT hand instrument is intended to be used for open surgery to cut, seal, coagulate, grasp, and dissect.

Seal & Cut mode:
The THUNDERBEAT hand instrument when used in combination with the Seal & Cut mode is indicated for open 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) or in any procedure in which cutting, vessel ligation (sealing and cutting), coagulation, grasping, and dissection is performed. The device has been designed to seal and cut vessels (up to and including 7 mm in diameter), tissue bundles, and lymphatics.

Seal mode:
The THUNDERBEAT hand instrument when used in combination with the Seal mode is indicated for open 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) or in any procedure in which vessel sealing, coagulation, grasping is performed. The device has been designed to seal vessels (up to and including 7 mm in diameter), tissue bundles, and lymphatics.

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

3. THUNDERBEAT Type S Hand Instruments TB-0520FCS/TB-0535FCS/TB-0545FCS
The THUNDERBEAT Type S 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 Type S 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 Type S 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 Type S 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.

4. THUNDERBEAT Open Fine Jaw TB-0009OF
The THUNDERBEAT Open Fine Jaw hand instrument is intended to be used for open surgery to cut, seal, coagulate, grasp, and dissect.

Seal & Cut mode:
The THUNDERBEAT Open Fine Jaw hand instrument when used in combination with the Seal & Cut mode is indicated for open, general surgery (including plastic and reconstructive, etc.) or in any procedure in which cutting, vessel ligation (sealing and cutting), coagulation, grasping, and dissection is performed. The device has been designed to seal and cut vessels (up to and including 7 mm in diameter), tissue bundles, and lymphatics.

This mode is also indicated for open ENT procedure in adults (thyroidectomy, parathyroidectomy, parotidectomy, and tonsillectomy) for only ligation (sealing and cutting) of vessels, lymphatics and tissue bundles 2-3mm*1 away from unintended thermally sensitive structures such as nerves and parathyroid glands.

Seal mode:
The THUNDERBEAT Open Fine Jaw hand instrument when used in combination with the Seal mode is indicated for open, general surgery (including plastic and reconstructive, etc.) or in any procedure in which vessel sealing, coagulation, grasping is performed. The device has been designed to seal vessels (up to and including 7 mm in diameter), tissue bundles, and lymphatics.

This mode is also indicated for open ENT procedure in adults (thyroidectomy, parathyroidectomy, parotidectomy, and tonsillectomy) for sealing of vessels, lymphatics and tissue bundles 2-3mm*1 away from unintended thermally sensitive structures such as nerves and parathyroid glands.

The THUNDERBEAT Open Fine Jaw hand instrument has not been shown to be effective for tubal sterilization or tubal coagulation for sterilization procedures, and should not be used for these procedures.
*1 It should be extended appropriately depending on the operation situation.

5. THUNDERBEAT Open Fine Jaw Type X TB-0009OFX
The THUNDERBEAT Open Fine Jaw Type X hand instrument is intended to be used for open surgery to cut, seal, coagulate, grasp, and dissect.

Seal & Cut mode:
The THUNDERBEAT Open Fine Jaw Type X hand instrument when used in combination with the Seal & Cut mode is indicated for open, general surgery (including plastic and reconstructive, etc.) or in any procedure in which cutting, vessel ligation (sealing and cutting), coagulation, grasping, and dissection is performed. The device has been designed to seal and cut vessels (up to and including 7 mm in diameter), tissue bundles, and lymphatics.
This mode is also indicated for open ENT procedure in adults (thyroidectomy, parathyroidectomy, parotidectomy, radical neck dissection, and tonsillectomy) for only ligation (sealing and cutting) of vessels, lymphatics and tissue bundles greater than 3 mm away from unintended thermally sensitive structures such as nerves and parathyroid glands.

Seal mode:
The THUNDERBEAT Open Fine Jaw Type X hand instrument when used in combination with the Seal mode is indicated for open, general surgery (including plastic and reconstructive, etc.) or in any procedure in which vessel sealing, coagulation, grasping is performed. The device has been designed to seal vessels (up to and including 7 mm in diameter), tissue bundles, and lymphatics.

This mode is also indicated for open ENT procedure in adults (thyroidectomy, parathyroidectomy, parotidectomy, radical neck dissection, and tonsillectomy) for sealing of vessels, lymphatics and tissue bundles greater than 3 mm away from unintended thermally sensitive structures such as nerves and parathyroid glands.

The THUNDERBEAT Open Fine Jaw Type X hand instrument has not been shown to be effective for tubal sterilization or tubal coagulation for sterilization procedures, and should not be used for these procedures.

6. SONICBEAT SB-0545PC, 0535PC, 0545IC, 0535IC, 0520IC, 0510IC, SB-0545FC, 0535FC and 0520FC
The SONICBEAT is intended to be used for open, laparoscopic (including single-site surgery), and general surgery to cut (dissect), coagulate, or grasp soft tissue or to ligate (seal and cut) vessels in gynecologic, thoracic, urologic, and endoscopic surgical procedures.

These devices have been designed to seal and cut vessels up to and including 5mm in diameter.

The SONICBEAT has not been shown to be effective for tubal sterilization or tubal coagulation for sterilization procedures, and should not be used for these procedures.

7. THUNDERBEAT Transducer TD-TB400
The THUNDERBEAT Transducer (TD-TB400) is intended to be used for open, laparoscopic (including single-site surgery), and endoscopic surgery to cut (dissect) or coagulate soft tissue or to ligate (seal and cut) vessels.

8. SONICBEAT Transducer TD-SB400
The SONICBEAT Transducer (TD-SB400) is intended to be used for open, laparoscopic (including single-site surgery), and endoscopic surgery to cut (dissect) or coagulate soft tissue or to ligate (seal and cut) vessels.

9. SONICBEAT Footswitch Connector MAJ-2412
This product is intended to be used to connect a SONICBEAT footswitch to an Ultrasonic Bipolar Generator and to communicate switch signals.

10. POWER CORD US 4.5m MAJ-2387
The power cord has been designed to be used for supplying power to Olympus equipment.

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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Date Prepared: August 3, 2021
K211838

510(k) Summary
ULTRASONIC BIPOLAR GENERATOR USG-410 with accessories

GENERAL INFORMATION

Applicant:	OLYMPUS MEDICAL SYSTEMS CORP. 2951 Ishikawa-cho, Hachioji-shi, Tokyo, Japan 192-8507 Establishment Registration Number: 8010047
Manufacturer:	Shirakawa Olympus Co., Ltd. 3-1 Okamiyama, Odakura, Nishigo-mura, Nishishirakawa-gun, Fukushima 961-8061, Japan Establishment Registration Number: 3002808148 Aomori Olympus Co., Ltd. 2-248-1 okkonoki kuroishi-shi aomori, Japan 036-0357 Establishment Registration Number: 9614641
510(k) Submitter:	Olympus Surgical Technologies of America 800 West Park Drive Westborough, MA 01581
Establishment Registration Number:	3003790304
Contact Person:	Anne-Marie Keefe Program Manager, Regulatory Affairs

DEVICE DESCRIPTION

Model No.	Device Name	Product Classification
USG-410	ULTRASONIC BIPOLAR GENERATOR	GEI (878.4400) LFL (Unclassified)
MAJ-2387	POWER CORD US 4.5m	

Active Accessory List

Model No.	Device Name	Product Classification
TB-0920OE	THUNDERBEAT Open Extended Jaw	GEI (878.4400) LFL (Unclassified)
TB-0520FCS	THUNDERBEAT Type S 5mm, 20cm, Front-actuated Grip	GEI (878.4400) LFL (Unclassified)
TB-0535FCS	THUNDERBEAT Type S 5mm, 35cm, Front-actuated Grip	
TB-0545FCS	THUNDERBEAT Type S 5mm, 45cm, Front-actuated Grip	
TB-0009OF	THUNDERBEAT Open Fine Jaw	GEI (878.4400) LFL (Unclassified)
TB-0009OFX	THUNDERBEAT Open Fine Jaw Type X	GEI (878.4400) LFL (Unclassified)
SB-0545PC	SONICBEAT 5mm, 45cm, Pistol Grip	LFL (Unclassified)
SB-0535PC	SONICBEAT 5mm, 35cm, Pistol Grip	
SB-0545IC	SONICBEAT 5mm, 45cm, Inline Grip	
SB-0535IC	SONICBEAT 5mm, 35cm, Inline Grip	
SB-0520IC	SONICBEAT 5mm, 20cm, Inline Grip	
SB-0510IC	SONICBEAT 5mm, 10cm, Inline Grip	
SB-0545FC	SONICBEAT 5 mm, 45cm, Front-actuated Grip	
SB-0535FC	SONICBEAT 5 mm, 35cm, Front-actuated Grip	
SB-0520FC	SONICBEAT 5 mm, 20cm, Front-actuated Grip	
TD-TB400	THUNDERBEAT Transducer	GEI (878.4400) LFL (Unclassified)
TD-SB400	SONICBEAT Transducer	LFL (Unclassified)

Miscellaneous accessories list

Model No.	Device Name	Product Classification
MAJ-2412	SONICBEAT Footswitch Connector	LFL (Unclassified)
MAJ-1869	Footswitch for SONICBEAT	LFL (Unclassified)

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:	ULTRASONIC BIPOLAR GENERATOR
Generic/Common Name:	Ultrasonic and electrosurgical device

PREDICATE DEVICES

Predicate Device*	510(k) No.
Surgical Tissue Management System	
Ultrasonic Generator USG-400 (primary predicate)	K172691
Electrosurgical Generator ESG-400	K141225
Active accessory	
THUNDERBEAT Open Extended Jaw TB-0920OE	K132703
THUNDERBEAT Type S 5mm, 20cm, Front-actuated Grip TB-0520FCS	K172610
THUNDERBEAT Type S 5mm, 35cm, Front-actuated Grip TB-0535FCS	
THUNDERBEAT Type S 5mm, 45cm, Front-actuated Grip TB-0545FCS	
THUNDERBEAT Open Fine Jaw TB-0009OF	K151743
THUNDERBEAT Open Fine Jaw Type X TB-0009OFX	K192103
SONICBEAT 5mm, 45cm, Pistol Grip SB-0545PC	K111202
SONICBEAT 5mm, 35cm, Pistol Grip SB-0535PC	
SONICBEAT 5mm, 45cm, Inline Grip SB-0545IC	
SONICBEAT 5mm, 35cm, Inline Grip SB-0535IC	
SONICBEAT 5mm, 20cm, Inline Grip SB-0520IC	
SONICBEAT 5mm, 10cm, Inline Grip SB-0510IC	
SONICBEAT 5 mm, 45cm, Front-actuated Grip SB-0545FC	
SONICBEAT 5 mm, 35cm, Front-actuated Grip SB-0535FC	
SONICBEAT 5 mm, 20cm, Front-actuated Grip SB-0520FC	
THUNDERBEAT Transducer TD-TB400	K111202
SONICBEAT Transducer TD-SB400	K111202
Miscellaneous accessory	
Footswitch for SONICBEAT MAJ-1869	K111202

*510(k) Submitter: OLYMPUS MEDICAL SYSTEMS CORP.

Product Description

The Electrosurgical & Ultrasonic Generator (USG-410) is intended to be used with the THUNDERBEAT Transducer, the SONICBEAT Transducer, the THUNDERBEAT 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.

USG-410 is the successor model of USG-400, with the addition of the function of ESG-400 related to THUNDERBEAT to generate combined ultrasonic and bipolar energy as the dedicated standalone generator. It is intended to be used with the same legacy marketed

devices including THUNDERBEAT series and SONICBEAT series which are compatible with the Surgical Tissue Management System (STMS).

The USG-410 can be used with a variety of legally marketed active and miscellaneous accessories including THUNDERBEAT series and SONICBEAT series, transducers, and footswitches. The THUNDERBEAT and SONICBEAT instruments are functional devices capable of vessel sealing and cutting, tissue coagulating and cutting, grasping, dissecting.
The THUNDERBEAT and the SONICBEAT have handswitches. Pressing the handswitches leads to controlling the output. The control signals are sent to the USG-410 via the signal lines in the Transducer cords of the Transducers. Output is also controllable with the Footswitches.

Comparison of Technological Characteristics

Generator

The subject of this 510(k) submission is the USG-410 system which is substantially equivalent to the predicate Surgical Tissue Management System (STMS), which is composed of two generators (USG-400 and ESG-400). The USG-410 system is based on the technology and the performance of the existing STMS and is compatible with the same accessories.

The following design changes were made to the devices:

- Dedicated standalone generator
- Modified sealing algorithm

Active and Miscellaneous accessories

The purpose of the submission for the subject accessories is to demonstrate new generator compatibility with the introduction of the modified sealing algorithm. In addition to the proposed compatibility, any minor modifications, which did not affect safety and effectiveness of the subject device, made to the subject accessories from post-510(k) clearance are indicated. Except for the proposed compatibility and minor modifications, (including the change in stainless steel (SUS304) for inner and outer pipes for the THUNDERBEAT and SONCIBEAT instruments and change in handle grip design from rear to front actuation) there are no other changes to technological features and direction for use of the cleared devices.

Indications for use

1. ULTRASONIC BIPOLAR GENERATOR USG-410

The Electrosurgical & Ultrasonic Generator (USG-410) is intended to be used with the THUNDERBEAT Transducer, the SONICBEAT Transducer, the THUNDERBEAT 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.

2. THUNDERBEAT Open Extended Jaw TB-0920OE

The THUNDERBEAT hand instrument is intended to be used for open surgery to cut, seal, coagulate, grasp, and dissect.

Seal & Cut mode:
The THUNDERBEAT hand instrument when used in combination with the Seal & Cut mode is indicated for open 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) or in any procedure in which cutting, vessel ligation (sealing and cutting), coagulation, grasping, and dissection is performed. The device has been designed to seal and cut vessels (up to and including 7 mm in diameter), tissue bundles, and lymphatics.

Seal mode:
The THUNDERBEAT hand instrument when used in combination with the Seal mode is indicated for open 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) or in any procedure in which vessel sealing, coagulation, grasping is performed. The device has been designed to seal vessels (up to and including 7 mm in diameter), tissue bundles, and lymphatics.

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

3. THUNDERBEAT Type S Hand Instruments TB-0520FCS/TB-0535FCS/TB-0545FCS

The THUNDERBEAT Type S 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 Type S 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 Type S 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 Type S 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.

4. THUNDERBEAT Open Fine Jaw TB-0009OF

The THUNDERBEAT Open Fine Jaw hand instrument is intended to be used for open surgery to cut, seal, coagulate, grasp, and dissect.

Seal & Cut mode:

The THUNDERBEAT Open Fine Jaw hand instrument when used in combination with the Seal & Cut mode is indicated for open, general surgery (including plastic and reconstructive, etc.) or in any procedure in which cutting, vessel ligation (sealing and cutting), coagulation, grasping, and dissection is performed. The device has been designed to seal and cut vessels (up to and including 7 mm in diameter), tissue bundles, and lymphatics.

This mode is also indicated for open ENT procedure in adults (thyroidectomy, parathyroidectomy, parotidectomy, and tonsillectomy) for only ligation (sealing and cutting) of vessels, lymphatics and tissue bundles 2-3mm*1 away from unintended thermally sensitive structures such as nerves and parathyroid glands.

Seal mode:

The THUNDERBEAT Open Fine Jaw hand instrument when used in combination with the Seal mode is indicated for open, general surgery (including plastic and reconstructive, etc.) or in any procedure in which vessel sealing, coagulation, grasping is performed. The device has been designed to seal vessels (up to and including 7 mm in diameter), tissue bundles, and lymphatics.

This mode is also indicated for open ENT procedure in adults (thyroidectomy, parathyroidectomy, parotidectomy, and tonsillectomy) for sealing of vessels, lymphatics and tissue bundles 2-3mm*1 away from unintended thermally sensitive structures such as nerves and parathyroid glands.

The THUNDERBEAT Open Fine Jaw hand instrument has not been shown to be effective for tubal sterilization or tubal coagulation for sterilization procedures, and should not be used for these procedures.

*1 It should be extended appropriately depending on the operation situation.

5. THUNDERBEAT Open Fine Jaw Type X TB-0009OFX

The THUNDERBEAT Open Fine Jaw Type X hand instrument is intended to be used for open surgery to cut, seal, coagulate, grasp, and dissect.

Seal & Cut mode:
The THUNDERBEAT Open Fine Jaw Type X hand instrument when used in combination with the Seal & Cut mode is indicated for open, general surgery (including plastic and reconstructive, etc.) or in any procedure in which cutting, vessel ligation (sealing and cutting), coagulation, grasping, and dissection is performed. The device has been designed to seal and cut vessels (up to and including 7 mm in diameter), tissue bundles, and lymphatics.
This mode is also indicated for open ENT procedure in adults (thyroidectomy, parathyroidectomy, parotidectomy, radical neck dissection, and tonsillectomy) for only ligation (sealing and cutting) of vessels, lymphatics and tissue bundles greater than 3 mm away from unintended thermally sensitive structures such as nerves and parathyroid glands.
Seal mode:
The THUNDERBEAT Open Fine Jaw Type X hand instrument when used in combination with the Seal mode is indicated for open, general surgery (including plastic and reconstructive, etc.) or in any procedure in which vessel sealing, coagulation, grasping is performed. The device has been designed to seal vessels (up to and including 7 mm in diameter), tissue bundles, and lymphatics.
This mode is also indicated for open ENT procedure in adults (thyroidectomy, parathyroidectomy, parotidectomy, radical neck dissection, and tonsillectomy) for sealing of vessels, lymphatics and tissue bundles greater than 3 mm away from unintended thermally sensitive structures such as nerves and parathyroid glands.

The THUNDERBEAT Open Fine Jaw Type X hand instrument has not been shown to be effective for tubal sterilization or tubal coagulation for sterilization procedures, and should not be used for these procedures.

6. SONICBEAT SB-0545PC, 0535PC, 0545IC, 0535IC, 0520IC, 0510IC, SB-0545FC, 0535FC and 0520FC

The SONICBEAT is intended to be used for open, laparoscopic (including single-site surgery), and general surgery to cut (dissect), coagulate, or grasp soft tissue or to ligate (seal and cut) vessels in gynecologic, thoracic, urologic, and endoscopic surgical procedures.

These devices have been designed to seal and cut vessels up to and including 5mm in diameter.

The SONICBEAT has not been shown to be effective for tubal sterilization or tubal coagulation for sterilization procedures, and should not be used for these procedures.

7. THUNDERBEAT Transducer TD-TB400

The THUNDERBEAT Transducer (TD-TB400) is intended to be used for open, laparoscopic (including single-site surgery), and endoscopic surgery to cut (dissect) or coagulate soft tissue or to ligate (seal and cut) vessels.

8. SONICBEAT Transducer TD-SB400
The SONICBEAT Transducer (TD-SB400) is intended to be used for open, laparoscopic (including single-site surgery), and endoscopic surgery to cut (dissect) or coagulate soft tissue or to ligate (seal and cut) vessels.

9. SONICBEAT Footswitch Connector MAJ-2412
This product is intended to be used to connect a SONICBEAT footswitch to an Ultrasonic Bipolar Generator and to communicate switch signals.

10. POWER CORD US 4.5m MAJ-2387
The power cord has been designed to be used for supplying power to Olympus equipment.

Compliance to Voluntary Standards

The following voluntary standards have been applied to the subject devices respectively:

ANSI AAMI ES60601-1:2005/(R)2012 and A1:2012
IEC60601-1-2: 2014
IEC60601-2-2:2017
IEC60601-2-18:2009
ISO10993-1:2009ISO10993-5: 2009
ISO10993-10: 2010
ISO10993-11: 2017
ISO11135:2014
ISO10993-7: 2008
ISO11607-1: 2006
ISO11607-2: 2006
ASTM F1980-16
ISO14971:2007/ 2019

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 Performance Testing

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

1. Bench Testing

Item	Contents
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.
Ex-vivo Max Temperature of Jaw	*Ex-vivo* max temperature of the jaw of both the subject and predicate devices was tested to compare surface temperatures of both devices.

2. Animal Test

Item	Contents
Chronic Animal Study	Chronic animal study of porcine subjects 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).
Acute Animal Study	Acute animal study of porcine subjects 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).

The subject generator has been bench tested and verified / validated to meet design specifications and user requirements to ensure the device performs as intended. Testing included:

- Cutting and sealing
- Verifying the modified sealing algorithm
- Compatibility with listed accessories

Preclinical: Evidence obtained from preclinical studies as noted above demonstrate that the device performs substantially equivalent to the predicate device in relevant aspects associated with tissue effects and thermal effects.

3. Biocompatibility Evaluation

The USG-410 does not contain components that come directly or indirectly in patient contact. Biocompatibility testing according to ISO 10993 for these components is not required.

Biocompatibility evaluation of the patient contacting accessories was successfully established previously for the predicate devices according to ISO 10993-1 Biological Evaluation of Medical Devices-Part 1: Evaluation and Testing. There have been no changes that have impacted the established biocompatibility.

4. Electrical safety and electromagnetic compatibility (EMC)
Electrical safety and EMC performance testing have been confirmed for the subject USG-410 to be in compliance with the relevant requirements as noted below. The active accessories are unchanged from the prior clearance.

- IEC60601-1:2005+A1 Medical electrical equipment – Part 1: General requirements for basic safety and essential performance

- IEC60601-2-2:2017 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. (General Plastic Surgery/General Hospital)

- IEC60601-1-2:2014 Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests (Edition 3)

5. Software Verification and Validation Testing
Software testing has been performed and documented to be in compliance with the FDA guidance "Guidance for the Content of Premarket Submissions for Software contained in medical devices" and "Content of Premarket Submissions for Management of Cybersecurity in Medical Devices".

6. Risk Analysis
Risk analysis for the subject device was conducted in accordance with established in-house acceptance criteria based on ISO 14971. The design verification tests and their acceptance criteria were identified and performed as a result of this risk analysis assessment.

In the risk management process, the human factors validation testing was also performed in accordance with the FDA Guidance, "Applying Human Factors and Usability Engineering to Medical Devices". In terms of human factors, an assessment of applicable adverse events along with a review of the overall risk analysis was conducted. These assessments confirmed that there was no unacceptable user-related residual risk for the ULTRASONIC BIPOLAR GENERATOR USG-410 and accessories.

7. Clinical Testing
Clinical testing was not applicable and not performed.

Substantial Equivalence

The predicate STMS is composed of two generators, USG-400 and ESG-400. The subject device, USG-410, integrates these individual device functions into one unit except conventional monopolar and bipolar function. Additionally, the USG-410 has equivalent output as USG-400/ESG-400 to seal vessels up to 7 mm, while a modified sealing algorithm has been adapted for USG-410 to control the RF Bipolar output.

The indications for use, principles of operation, fundamental technology of the Ultrasonic Bipolar generator USG-410 are identical to the predicate STMS. USG-410 has compatibility with the existing THUNDERBEAT and SONICBEAT. The indicated patient population and procedures are also identical to the predicate devices. To achieve new generator compatibility for MAJ-1869, MAJ-2412 is added to connect a footswitch to USG-410. However, MAJ-1869's functions, materials, and principles of operation are identical to the predicate device.

The purpose of the submission for the subject accessories is to indicate new generator compatibility. There are no technological design changes for these accessories and the direction for use is the same as the cleared devices.

The subject USG-410 has been verified and validated to be equivalent in sealing performance, thermal spread and coagulation (ex vivo burst pressure tests and in vivo animal acute and survival study, hemostasis), when compared to the predicate STMS. As the performance test results demonstrate equivalent performance, we believe there are no new concerns or modified existing risks regarding safety and effectiveness of the subject devices.

Conclusion

In summary, the ULTRASONIC BIPOLAR GENERATOR USG-410 and accessories are substantially equivalent to the predicate devices and present no new questions of safety or effectiveness.