October 7, 2025

Olympus Medical Systems Corporation
% Elizabeth Greene
Program Manager
Olympus Corporation of the Americas
800 West Park Drive
Westborough, Massachusetts 01581

Re: K252150
Trade/Device Name: Ultrasonic Bipolar Generator (USG-410); Reuseable Cordless Transducer (TD-410); THUNDERBEAT II Shears with Ultrasonic Mode, 5mm, 45cm (TB2-0545FC); THUNDERBEAT II Shears with Ultrasonic Mode, 5mm, 35cm (TB2-0535FC); THUNDERBEAT II Shears with Ultrasonic Mode, 5mm, 25cm (TB2-0525FC); THUNDERBEAT II Shears with Ultrasonic Mode, 5mm, 20cm (TB2-0520FC)
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical cutting and coagulation device and accessories
Regulatory Class: Class II
Product Code: GEI, LFL
Dated: July 9, 2025
Received: July 9, 2025

Dear Elizabeth Greene:

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.

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: 2025.10.07 14:24:29 -04'00'

Colin Kejing Chen
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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K252150

Device Name
Ultrasonic Bipolar Generator(USG-410);Reusable Cordless Transducer(TD-410);THUNDERBEAT II Shears with Ultrasonic Mode, 5mm,45cm(TB2-0545FC);THUNDERBEAT II Shears with Ultrasonic Mode, 5mm,35cm(TB2-0535FC);THUNDERBEAT II Shears with Ultrasonic Mode, 5mm,25cm(TB2-0525FC);THUNDERBEAT II Shears with Ultrasonic Mode, 5mm,20cm(TB2-0520FC)

Indications for Use *(Describe)*
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.

The Reusable Cordless Transducer (TD-410) 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.

The THUNDERBEAT II Shears with Ultrasonic Mode (TB2-0520FC, TB2-0525FC, TB2-0535FC, TB2-0545FC) are intended to be used for open, laparoscopic, and endoscopic surgery to cut, seal, coagulate, grasp, and dissect.

The THUNDERBEAT II Shears with Ultrasonic Mode are indicated for general, plastic and reconstructive, gynecologic, urologic, thoracic, and other open, laparoscopic and endoscopic procedures.

The THUNDERBEAT II Shears with Ultrasonic Mode have been designed to seal and cut vessels up to and including 7mm in diameter, tissue bundles and lymphatics using with the Seal & Cut mode or the Seal mode.

The THUNDERBEAT II shears with Ultrasonic Mode have been designed to seal and cut vessels up to and including 3mm in diameter, tissue bundles and lymphatics using with the Ultrasonic mode.

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.

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510(k) Summary

For

THUNDERBEAT II (TB2-0545FC, TB2-0535FC, TB2-0525FC, TB2-0520FC)
Reusable Cordless Transducer (TD-410)
Ultrasonic Bipolar Generator (USG-410)

General Information

Applicant:	OLYMPUS MEDICAL SYSTEMS CORP. 2951 Ishikawa-cho, Hachioji-shi, Tokyo, Japan 192-8507 Phone: (+81) 42-642-2111 Fax: (+81) 42-642-2307 Establishment Registration Number: 8010047
Manufacturer:	Shirakawa Olympus Co., Ltd. 3-1 Okamiyama, Odakura, Nishigo-mura, Nishishirakawa-gun, Fukushima 961-8061, Japan Aomori Olympus Co., Ltd. 2-248-1 Okkonoki Kuroishi-Shi Aomori, 036-0357, Japan Olympus Surgical Technologies of America 9600 Louisiana Avenue North Brooklyn Park, Minnesota 55445
510(k) Submitter:	Olympus Corporation of the Americas 800 West Park Drive Westborough, MA 01581
Establishment Registration Number:	2429304
Contact Person:	Elizabeth Greene Program Manager Mobile: (772) 254-3793 Email: elizabeth.greene@olympus.com
Date Prepared:	July 9, 2025

Device Description

Device Name:	THUNDERBEAT II
Model Name:	TB2-0545FC, TB2-0535FC, TB2-0525FC, TB2-0520FC
Generic/Common Name:	Ultrasonic and electrosurgical devices
Regulation Number:	21 CFR 878.4400
Regulatory Class:	Class II
Classification Name:	Electrosurgical cutting and coagulation and accessories
Product Codes:	GEI, LFL
Review Panel:	General & Plastic Surgery

Device Name:	Reusable Cordless Transducer
Model Name:	TD-410
Generic/Common Name:	Ultrasonic and electrosurgical devices
Regulation Number:	21 CFR 878.4400
Regulatory Class:	Class II
Classification Name:	Electrosurgical cutting and coagulation and accessories
Product Codes:	GEI, LFL
Review Panel:	General & Plastic Surgery

Device Name:	Ultrasonic Bipolar Generator
Model Name:	USG-410
Generic/Common Name:	Ultrasonic and electrosurgical devices
Regulation Number:	21 CFR 878.4400
Regulatory Class:	Class II
Classification Name:	Electrosurgical cutting and coagulation and accessories
Product Codes:	GEI, LFL
Review Panel:	General & Plastic Surgery

Predicate Device

Device Name	510(k) Submitter	510(k) No.
THUNDERBEAT Type S TB-0520FCS, TB-0535FCS, TB-0545FCS	Olympus Medical Systems Corp.	K211838
SONICBEAT SB-0520FC, SB-0535FC, SB-0545FC		
THUNDERBEAT Transducer TD-TB400		
Ultrasonic Bipolar Generator USG-410		

Indications for Use

Table 1 details the Indications for Use for the subject devices.

Table 1. Indications for Use for THUNDERBEAT II, Reusable Cordless Transducer, and Ultrasonic Bipolar Generator

Device	Indications for Use
THUNDERBEAT II TB2-0545FC, TB2-0535FC, TB2-0525FC, TB2-0520FC	The THUNDERBEAT II Shears with Ultrasonic Mode (TB2-0520FC, TB2-0525FC, TB2-0535FC, TB2-0545FC) are intended to be used for open, laparoscopic, and endoscopic surgery to cut, seal, coagulate, grasp, and dissect. The THUNDERBEAT II Shears with Ultrasonic Mode are indicated for general, plastic and reconstructive, gynecologic, urologic, thoracic, and other open, laparoscopic and endoscopic procedures. The THUNDERBEAT II Shears with Ultrasonic Mode have been designed to seal and cut vessels up to and including 7mm in diameter, tissue bundles and lymphatics using with the Seal & Cut mode or the Seal mode. The THUNDERBEAT II shears with Ultrasonic Mode have been designed to seal and cut vessels up to and including 3mm in diameter, tissue bundles and lymphatics using with the Ultrasonic mode.
Reusable Cordless Transducer TD-410	The Reusable Cordless Transducer (TD-410) 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.
Ultrasonic Bipolar Generator	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.

Device Description

The following devices are the subject of this premarket (510(k)) submission:

- **THUNDERBEAT II (Model Numbers: TB2-0545FC, TB2-0535FC, TB2-0525FC, TB2-0520FC)** – Hand instruments used with an ultrasonic generator and transducer capable of sealing, cutting, grasping and dissecting vessels, tissue bundles, and lymphatic tissue up to 7mm in diameter during open, laparoscopic, and endoscopic surgical procedures. THUNDERBEAT II hand instruments are available in four (4) shaft sizes: 20cm, 25cm, 35cm, and 45cm.
- **Reusable Cordless Transducer (Model Number: TD-410)** – A transducer used with the THUNDERBEAT II hand instruments and ultrasonic generator to dissect and/or coagulate soft tissue, or ligate (seal and cut) soft tissue.
- **Ultrasonic Bipolar Generator (Model Number: USG-410)** – An ultrasonic bipolar generator used with the compatible hand instruments and transducers to dissect and/or coagulate soft tissue, or ligate (seal and cut) soft tissue. Identical and unchanged from K211838, but modified when accessory MAJ-2467 is used to upgrade USG-410 software version to allow compatibility with THUNDERBEAT II hand instruments.
    - **Update Tool for USG-410 (Model Number: MAJ-2467)** – A function activation portable memory key accessory used to upgrade the software version of USG-410 to allow compatibility with THUNDERBEAT II hand instruments.

Comparison of Technological Characteristics

Table 2 compares the THUNDERBEAT II hand instruments to the THUNDERBEAT Type S and SONICBEAT hand instruments with respect to intended use, and technological characteristics, providing detailed information regarding the basis for the determination of substantial equivalence.

Table 2. Comparison of THUNDERBEAT II to the predicate devices

Feature/ Technological Characteristics	Subject Device	Primary Predicate Device	Secondary Predicate Device
Regulatory			
Device Name	THUNDERBEAT II	THUNDERBEAT Type S	SONICBEAT
Model Number	TB2-0545FC, TB2-0535FC TB2-0525FC, TB2-0520FC	TB-0520FCS, TB-0535FCS, TB-0545FCS	SB-0545FC, SB-0535FC, SB-0520FC
Legal Manufacturer	OLYMPUS MEDICAL SYSTEMS CORP.	OLYMPUS MEDICAL SYSTEMS CORP.	OLYMPUS MEDICAL SYSTEMS CORP.
Regulatory Decision	This submission	K211838	K211838
Regulation No.	21 CFR 878.4400	21 CFR 878.4400	Unclassified
Regulation Name	Electrosurgical, Cutting & Coagulation & Accessories	Electrosurgical, Cutting & Coagulation & Accessories	Unclassified
Product Code	GEI, LFL	GEI, LFL	LFL
Regulatory Class	II	II	Unclassified
Classification Panel	General and Plastic Surgery	General and Plastic Surgery	General and Plastic Surgery
Indications for Use	The THUNDERBEAT II Shears with Ultrasonic Mode (TB2-0520FC, TB2-0525FC, TB2-0535FC, TB2-0545FC) are intended to be used for open, laparoscopic, and endoscopic surgery to cut, seal, coagulate, grasp, and dissect. The THUNDERBEAT II Shears with Ultrasonic Mode are indicated for general, plastic and reconstructive, gynecologic, urologic, thoracic, and other open, laparoscopic and endoscopic procedures. The THUNDERBEAT II Shears with Ultrasonic Mode have been designed to seal and cut vessels up to and including 7mm in diameter, tissue bundles and lymphatics using with the Seal & Cut mode or the Seal mode. The THUNDERBEAT II shears with Ultrasonic Mode have been designed to seal and cut vessels up to and including 3mm in diameter, tissue	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 TUNDERBEAT Type S hand instrument 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.	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.

Feature/ Technological Characteristics	Subject Device	Primary Predicate Device	Secondary Predicate Device
	bundles and lymphatics using with the Ultrasonic mode.	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 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 7mm 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.	
Contraindications	The THUNDERBEAT II shears with Ultrasonic Mode have not been shown to be effective for tubal sterilization or tubal coagulation for sterilization procedures, and should not be used for these procedures.	Not Applicable	Not Applicable
Specifications			
Handle Design	Front-actuated grip with shaft body:	Front-actuated grip with shaft body:	Front-actuated grip with shaft body:
Grasping Part	Curved Tip Single Action	Curved Tip Single Action	Curved Tip Single Action
Shaft Lengths	20, 25, 35, 45 cm	20, 35, 45 cm	20, 35, 45 cm
Shaft Diameter	5.5mm	5.5mm	5.5mm

Feature/ Technological Characteristics	Subject Device	Primary Predicate Device	Secondary Predicate Device
Basic Principle	Used in combination with the reusable cordless transducer (TD-410) and ultrasonic bipolar generator (USG-410) Available operations include: **Combined ultrasonic and RF bipolar** – high frequency (HF) current is applied between the grasping section and the probe tip at the same time as the ultrasonic vibrations transmitted to the probe tip to seal, cut, and coagulate vessels and other tissues. **RF bipolar** – HF current is applied between the grasping section and the probe tip to seal and coagulate vessels and other tissues. **Ultrasonic** – ultrasonic vibrations transmitted to the probe tip to seal, cut, and coagulate vessels and other tissues.	Used in combination with an ultrasonic transducer (TD-TB400) and a generator (USG-410). Available operations include: **Combined ultrasonic and RF bipolar** –HF current is applied between the grasping section and the probe tip at the same time as the ultrasonic vibrations transmitted to the probe tip to seal, cut, and coagulate vessels and other tissues. **RF bipolar** – HF current is applied between the grasping section and the probe tip to seal and coagulate vessels and other tissues.	Used in combination with an ultrasonic transducer (TD-SB400) and a generator (USG-410). Available operations include: **Ultrasonic** – ultrasonic vibrations transmitted to the probe tip to seal, cut, and coagulate vessels and other tissues.
Cutting Mechanism	• **Seal & Cut mode:** Ultrasonic vibration • **Seal mode:** No cutting • **Ultrasonic mode:** Ultrasonic vibration	• **Seal & Cut mode:** Ultrasonic vibration • **Seal mode:** No cutting	• **VAR, MAX mode:** Ultrasonic vibration
Shelf Life	3 years	3 years	3 years
Sterilization	EO Sterilized; Single Use Only	EO Sterilized; Single Use Only	EO Sterilized; Single Use Only
Software	Not Applicable. Device does not contain software	Not Applicable. Device does not contain software	Not Applicable. Device does not contain software

Table 3 compares the Reusable Cordless Transducer to the THUNDERBEAT Transducer with respect to intended use, and technological characteristics, providing detailed information regarding the basis for the determination of substantial equivalence.

Table 3. Comparison of the Reusable Cordless Transducer to the predicate device

Feature/ Technological Characteristics	Subject Device	Predicate Device
Regulatory		
Device Name	Reusable Cordless Transducer	THUNDERBEAT Transducer
Model Number	TD-410	TD-TB400
Legal Manufacturer	OLYMPUS MEDICAL SYSTEMS CORP.	OLYMPUS MEDICAL SYSTEMS CORP.
Regulatory Decision	This submission	K211838
Regulation No.	21 CFR 878.4400	21 CFR 878.4400
Regulation Name	Electrosurgical, Cutting & Coagulation & Accessories	Electrosurgical, Cutting & Coagulation & Accessories
Product Code	GEI, LFL	GEI, LFL
Regulatory Class	II	II

Feature/ Technological Characteristics	Subject Device	Predicate Device
Classification Panel	General and Plastic Surgery	General and Plastic Surgery
Indications for Use	The Reusable Cordless Transducer (TD-410) 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.	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.
Specifications		
Body Design	Cordless	Transducer Cord
Enclosure Dimensions	Outer Diameter: 33mm Cord Length: Not Applicable	Outer Diameter: 33mm Cord Length: 3100mm
Basic Principle	• Converts electrical signal sent from the generator into mechanical vibration and transmits the ultrasonic vibration to the probe tip. • Transmits the HF current generated by the generator to the grasping section and the probe tip.	• Converts electrical signal sent from the generator into mechanical vibration and transmits the ultrasonic vibration to the probe tip. • Transmits the HF current generated by the generator to the grasping section and the probe tip.
Ultrasonic Frequency	47kHz	47kHz
Shelf Life	Not Applicable.	Not Applicable
Reprocessing	Applicable, multi-use, multi-patient device. Steam sterilization	Applicable, multi-use, multi-patient device. Steam sterilization
Software	Not Applicable. Device does not contain software	Not Applicable. Device does not contain software
Number of Cases	100 cases or 2 years since delivery, whichever comes first	100 cases or 1 year since delivery, whichever comes first

Table 4 compares the Ultrasonic Bipolar Generator to the Ultrasonic Bipolar Generator with respect to intended use, and technological characteristics, providing detailed information regarding the basis for the determination of substantial equivalence.

Table 4. Comparison of the Ultrasonic Bipolar Generator to the Predicate Device

Feature/ Technological Characteristics	Subject Device	Predicate Device
REGULATORY		
Device (Model) Name	Ultrasonic Bipolar Generator	Ultrasonic Bipolar Generator
Model Number	USG-410	USG-410
Legal Manufacturer	OLYMPUS MEDICAL SYSTEMS CORP.	OLYMPUS MEDICAL SYSTEMS CORP.
Regulatory Decision	This submission	K211838
Regulation No.	21 CFR 878.4400	21 CFR 878.4400
Regulation Name	Electrosurgical, Cutting & Coagulation & Accessories	Electrosurgical, Cutting & Coagulation & Accessories
Product Code	GEI, LFL	GEI, LFL
Regulatory Class	II	II
Classification Panel	General and Plastic Surgery	General and Plastic Surgery
Indications for Use	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	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

Feature/ Technological Characteristics	Subject Device	Predicate Device
	to cut (dissect) or coagulate soft tissue or to ligate (seal and cut) vessels.	to cut (dissect) or coagulate soft tissue or to ligate (seal and cut) vessels.
SPECIFICATIONS		
Touch Screen	Available	Available
Dimensions	370x100x360mm	370x100x360mm
Weight	9.0kg	9.0kg
Basic Principle	• Provides and controls electrical (RF) energy and ultrasonic energy for cutting and coagulation of tissue in open, laparoscopic and endoscopic surgery. • Drive current is transformed to ultrasonic energy through the compatible transducer and provided to the compatible hand instrument's probe in the form of mechanical vibration. • HF current is applied between the grasping section and the probe tip of the compatible hand instrument. • The following operations are available: o Combined Ultrasonic and RF Bipolar: HF current is applied at the same time as ultrasonic vibrations transmitted to the probe tip. o RF Bipolar: HF current is applied. o Ultrasonic: Ultrasonic vibrations are transmitted to the probe tip.	• Provides and controls electrical (RF) energy and ultrasonic energy for cutting and coagulation of tissue in open, laparoscopic and endoscopic surgery. • Drive current is transformed to ultrasonic energy through the compatible transducer and provided to the compatible hand instrument's probe in the form of mechanical vibration. • HF current is applied between the grasping section and the probe tip of the compatible hand instrument. • The following operations are available: o Combined Ultrasonic and RF Bipolar: HF current is applied at the same time as ultrasonic vibrations transmitted to the probe tip. o RF Bipolar: HF current is applied. o Ultrasonic: Ultrasonic vibrations are transmitted to the probe tip.
Power Supply, Voltage	100 to 120 VAC	100 to 120 VAC
Power Supply, Frequency	50/60Hz	50/60Hz
Power Supply, Max. Input Power (100 to 120 VAC)	350VA	350VA
Power Supply, Input	350VA	350VA
Display	Liquid crystal display	Liquid crystal display
Instrument Sockets	• Hand Instruments • Foot Switch	• Hand Instruments • Foot Switch
Hand Instrument Socket features	• Ultrasonic • Bipolar	• Ultrasonic • Bipolar
Compatible Hand Instruments	• THUNDERBEAT (K211838) • SONICBEAT (K211838) • THUNDERBEAT II (after software upgrade with MAJ-2467)	• THUNDERBEAT (K211838) • SONICBEAT (K211838)
Compatible Transducers	• THUNDERBEAT Transducer TD-TB400 (K211838) • SONICBEAT Transducer TD-SB400 (K211838) • Reuseable Cordless Transducer TD-410 (after software upgrade with MAJ-2467)	• THUNDERBEAT Transducer TD-TB400 (K211838) • SONICBEAT Transducer TD-SB400 (K211838)
Output Mode	**THUNDERBEAT:** • Seal & Cut (3 levels) • Seal (1 level) **SONICBEAT:** • VAR (3 levels)	**THUNDERBEAT:** • Seal & Cut (3 levels) • Seal (1 level) **SONICBEAT:** • VAR (3 levels)

Feature/ Technological Characteristics	Subject Device	Predicate Device
	• MAX (1 level) **THUNDERBEAT II** • Seal & Cut (3 levels) • Seal (1 level) • Ultrasonic (no level)	• MAX (1 level)
Ultrasonic Output	**THUNDERBEAT:** • Seal & Cut mode: ○ Energy Type: Ultrasonic+RF Bipolar ○ Frequency: 47kHz **SONICBEAT:** • MAX/VAR mode: ○ Energy Type: Ultrasonic ○ Frequency: 47kHz **THUNDERBEAT II** • Seal & Cut mode: ○ Energy Type: Ultrasonic+RF Bipolar ○ Frequency: 47kHz • Ultrasonic mode: ○ Energy Type: Ultrasonic ○ Frequency: 47kHz	**THUNDERBEAT:** • Seal & Cut mode: ○ Energy Type: Ultrasonic+RF Bipolar ○ Frequency: 47kHz **SONICBEAT:** • MAX/VAR mode: ○ Energy Type: Ultrasonic ○ Frequency: 47kHz
RF Bipolar	**Seal & Cut mode:** • Frequency: 380kHz • Max Voltage: 150Vp • Rated output power: 38W at 50Ω **Seal mode:** • Frequency: 380kHz • Max Voltage: 150Vp • Rated output power: 110W at 50Ω	**Seal & Cut mode:** • Frequency: 380kHz • Max Voltage: 150Vp • Rated output power: 38W at 50Ω **Seal mode:** • Frequency: 380kHz • Max Voltage: 150Vp • Rated output power: 110W at 50Ω
Duty Cycle	50% (30 sec. ON/ 30 sec. OFF)	50% (30 sec. ON/ 30 sec. OFF)
Universal Output, Bipolar, and Monopolar Sockets	Not Applicable	Not Applicable
Neutral electrodes	Not Applicable	Not Applicable
Type of protection Against Electric Shock	Class I	Class I
Degree of Protection Against Electric Shock	CF	CF
Essential Performance	The output can be turned ON/OFF in response to pressing of the output switch (hand switch/foot switch)	The output can be turned ON/OFF in response to pressing of the output switch (hand switch/foot switch)
Sterilization	Not Applicable	Not Applicable
Software	Contains Software	Contains Software

Compliance to Voluntary Standards

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

- ISO 15223-1
- ISO 7000
- ISO 7010

- ANSI AAMI ST98:2022
- ISO 10993-7 Second Ed. 2008-10-15
- ISO 11135 Second Ed. 2014-07-15
- ISO 11607-1 Second Ed. 2019-02
- ISO 11607-2 Second Ed. 2019-02
- ASTM F1980-21
- ISO 10993-1: Fifth Ed. 2018-08
- ISO 10993-5 Third Ed. 2009-06-01
- ISO 10993-10 Fourth Ed. 2021-11
- ISO 10993-11: Third Ed. 2017-09
- ISO 10993-12: Fifth Ed. 2021-01
- ISO 10993-17 Second Ed. 2023-09
- ISO 10993-18 Second Ed. 2020-01 Amendment 1 2022-05
- ISO 10993-23 First Ed. 2021-01
- IEC 62304 Edition 1.1 2015-06
- IEC 81001-5-1 Ed. 1.0 2021-12
- AAMI TIR57:2016
- ANSI AAMI ES 60601-1:2005/(R)2012 and A1:2012
- IEC 60601-1-2 Ed. 4.1 2020-09
- IEC 60601-1-6 Ed. 3.2 2020-07
- IEC 60601-4-2 Ed. 1.0 2016-05
- IEC 60601-2-2 Ed. 6.0 2017-03
- IEC 60601-1-8 Ed. 2.2 2020-07 CONSOLIDATED VERSION
- ISO 14971:2019

Summary of Performance Testing

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

Reprocessing, Sterilization, and Shelf Life Validation

TB2-0545FC, TB2-0535FC, TB2-0525FC, TB2-0520FC sterilization is substantially equivalent to the predicate devices, TB-0520FCS, TB-0535FCS, TB-0545FC, SB-0545FC, SB-0535FC, SB-0520FC as demonstrated through validation. These subject devices have demonstrated stability for 3 years as verified through accelerated aging study with concurrent real time testing ongoing. The subject devices are sterile, single use medical devices and validated as safe and effective.

TD-410 reprocessing is substantially equivalent to the predicate device, TD-TB400 as demonstrated through validation. TD-410 is validated as safe and effective for reprocessing as detailed in the Instruction Manual with the following:

- Manual Cleaning with Endozime AW
- Autoclave Sterilization with the following sterilization accessories:
    - Stainless Steel Basket and Sterilization Wrap
    - Sterilization Pouches

- Drying time with the following sterilization accessories:
  - 60 minutes with Stainless Steel Basket and Sterilization Wrap
  - 40 minutes with Sterilization Pouches

USG-410 disinfection and cleaning instructions have demonstrated through comparative evaluation that the subject device can be effectively disinfected cleaned through surface wiping, substantially equivalent to the predicate device, USG-410.

Software Verification and Validation Testing

The following subject devices a of this premarket notification submission contain software and device software functions:

- **Ultrasonic Bipolar Generator (Model Number: USG-410)** – An ultrasonic bipolar generator used with the compatible hand instruments and transducers to dissect and/or coagulate soft tissue, or ligate (seal and cut) soft tissue. Identical and unchanged from K211838, but modified when accessory MAJ-2467 is used to upgrade USG-410 software version to allow compatibility with THUNDERBEAT II hand instruments.

Software verification and validation testing of USG-410 has been performed and documented in compliance with the FDA guidance "Guidance for the Content of Premarket Submissions for Device Software Functions" and "Cybersecurity in Medical Devices: Quality System Considerations and Content of Premarket Submissions."

Electrical Safety and Electromagnetic Compatibility (EMC)

Electrical safety and EMC performance testing for the subject devices of this 510(k) submission are confirmed to be in compliance with the relevant requirements as noted below.

- ANSI AAMI ES 60601-1:2005+A1:2012 Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
- IEC 60601-1-2:2014 Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests (Edition 4)
- IEC 60601-2-2: 2017 Medical electrical equipment - Part 2-2: Particular requirements for the basic safety and essential performance of high frequency surgical equipment and high frequency surgical accessories

Bench and Animal Testing

Bench testing in compliance with the FDA guidance, "Premarket Notification (510(k)) Submissions for Bipolar Electrosurgical Vessel Sealers for General Surgery" was conducted for the subject devices of this 510(k) submission to ensure that the subject device performs as intended and meets design specifications.

Risk Analysis

Risk analysis for the subject devices of this 510(k) submission was conducted in accordance with established in-house acceptance criteria based on ISO 14971:2019. 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, Olympus performed preliminary analysis and evaluation to identify user tasks, user interface components, and use issues of the subject devices of this 510(k) submission in accordance with the FDA Guidance, "Applying Human Factors and Usability Engineering to Medical Devices" issued on February 2, 2016. Olympus determined that human factors validation testing was required. Therefore, Olympus performed human factors validation and determined that risks have been mitigated effectively.

Clinical Testing

Clinical testing was not applicable and not performed.

Substantial Equivalence

Olympus has determined that the subject devices of this premarket notification submission, THUNDERBEAT II (Model Numbers: TB2-0545FC, TB2-0535FC, TB2-0525FC, TB2-0520FC), Reusable Cordless Transducer (Model Number: TD-410), and Ultrasonic Bipolar Generator (Model Number: USG-410) are substantially equivalent to the legally marketed predicate devices, THUNDERBEAT Type S, primary predicate device, and SONICBEAT, secondary predicate device (K211838), THUNDERBEAT Transducer (K211838), and Ultrasonic Bipolar Generator (K211838) for the following reasons:

- same intended use;
- technological characteristics (design, materials, and operations) are similar or identical to the predicate devices; and
- does not introduce any new or novel treatments or standard of care that differs from predicate devices in commercial use.

THUNDERBEAT II (Model Numbers: TB2-0545FC, TB2-0535FC, TB2-0525FC, TB2-0520FC)

The intended use, principles of operation, and fundamental technology of THUNDERBEAT II are identical to the predicate devices. The differences in indications for use are not a change from single use labeling to reusable, and is not a change from prescription (Rx) use to over the counter (OTC) use. Further, this change does not describe a new disease, condition, or patient population that the device is intended in diagnosing, treating, preventing, curing, or mitigating. The differences in specification are a result of product maturation. THUNDERBEAT II is designed to have support RF bipolar and ultrasonic outputs with one device. A risk-based assessment of these differences did not identify any new risks or significantly modified existing risks or raise new or different questions with respect to safety and effectiveness.

Reusable Cordless Transducer (Model Number: TD-410)

The intended use, principles of operation, and fundamental technology of Reusable Cordless Transducer are identical to the predicate device. These differences in specifications are a result of product maturation and functionality with THUNDERBEAT II are not a change from single use labeling

to reusable, and not a change from prescription (Rx) use to over the counter (OTC) use. Further, this change does not describe a new disease, condition, or patient population that the device is intended in diagnosing, treating, preventing, curing, or mitigating. A risk-based assessment of these differences did not identify any new risks or significantly modified existing risks or raise new or different questions with respect to safety and effectiveness.

Ultrasonic Bipolar Generator (Model Number: USG-410)

The intended use, principles of operation, fundamental technology of the Ultrasonic Bipolar Generator are identical to and unchanged from the predicate device. The differences in specifications include compatible hand instruments and compatible transducers, which are a result of product maturation. THUNDERBEAT II is designed to have support RF bipolar and ultrasonic outputs with one device. The compatibility with the new hand instruments and transducers introduced with this submission is possible via the accessory, MAJ-2467, which has been verified as safe and effective. This difference is not a change from single use labeling to reusable, and is not a change from prescription (Rx) use to over the counter (OTC) use. Further, this change does not describe a new disease, condition, or patient population that the device is intended in diagnosing, treating, preventing, curing, or mitigating. A risk-based assessment of these differences did not identify any new risks or significantly modified existing risks or raise new or different questions with respect to safety and effectiveness.

USG-410 has been verified and validated to be equivalent in electrical performance for use with compatible hand instruments and transducers to output image signals to cut (dissect) or coagulate soft tissue or to ligate (seal and cut) vessels in pen, laparoscopic (including single-site surgery), and endoscopic surgery. As the electrical safety and electromagnetic compatibility test results demonstrate equivalent performance, Olympus has determined there are no new concerns or modified existing risks regarding safety and effectiveness of the subject device.

Conclusion

The subject devices of this submission, THUNDERBEAT II (Model Numbers: TB2-0545FC, TB2-0535FC, TB2-0525FC, TB2-0520FC), Reusable Cordless Transducer (Model Number: TD-410), and Ultrasonic Bipolar Generator (Model Number: USG-410), have same intended use as corresponding predicate devices. Performance of the subject devices is substantially equivalent to the predicate devices and raises no new questions of safety or effectiveness. Therefore, the subject devices are substantially equivalent to the predicate devices for the requested indications for use.