July 1, 2026

Olympus Medical Systems Corp.
% Susan Lewandowski
Manager, Program Regulatory Affairs
Olympus Corporation of the Americas
800 W. Park Dr.
Westborough, Massachusetts 01581

Re: K254056
Trade/Device Name: THUNDERBEAT 5 mm, 45 cm, Front-actuated Grip Type S (TB-0545FCS);
THUNDERBEAT 5 mm, 35 cm, Front-actuated Grip Type S (TB-0535FCS);
THUNDERBEAT 5 mm, 20 cm, Front-actuated Grip Type S (TB-0520FCS)
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical Cutting And Coagulation Device And Accessories
Regulatory Class: Class II
Product Code: GEI, LFL
Dated: June 2, 2026
Received: June 2, 2026

Dear Susan Lewandowski:

We have reviewed your section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (the Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database available at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (Preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR Part 803) for devices or postmarketing safety reporting (21 CFR Part 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the Quality Management System Regulation (QMSR) (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

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

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-

assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Colin K. Chen -S

Digitally signed by Colin K. Chen -S
Date: 2026.07.01 15:18:48 -04'00'

Colin K. Chen, Ph.D.
Acting Assistant Director
DHT4A: Division of General Surgery Devices
OHT4: Office of Surgical and Infection Control Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

Indications for Use

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

K254056

Please provide the device trade name(s).

THUNDERBEAT 5 mm, 45 cm, Front-actuated Grip Type S (TB-0545FCS);
THUNDERBEAT 5 mm, 35 cm, Front-actuated Grip Type S (TB-0535FCS);
THUNDERBEAT 5 mm, 20 cm, Front-actuated Grip Type S (TB-0520FCS)

Please provide your Indications for Use below.

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.

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

- [x] Prescription Use (21 CFR 801 Subpart D)
- [ ] Over-The-Counter Use (21 CFR 801 Subpart C)

510(k) Summary

1. General Information

Date Prepared: June 26, 2026

510(K) submitter: **Olympus Medical Systems Corporation**
2951 Ishikawa-cho, Hachioji-shi, Tokyo Japan 192-8507

Contact: Norikiyo Shibata
Email: norikiyo.shibata@olympus.com

Correspondent: Olympus Surgical Technologies of America
800 West Park Drive, Westborough, MA 01581

Primary Contact: Susan Lewandowski
Email: susan.lewandowski@olympus.com

2. Device Information

Device Name: THUNDERBEAT Type S Hand Instrument
Model Name: TB-0520FCS, TB-0535FCS, TB-0545FCS
Common Name: Electrosurgical cutting and coagulation device
Classification: 878.4400 – Electrosurgical, Cutting & Coagulation & Accessories
Regulatory Class: II
Product Code: GEI – Electrosurgical, Cutting & Coagulation & Accessories
LFL – Instrument, Ultrasonic Surgical
Device Panel: General and Plastic Surgery

3. Predicate Device Information

Device Name	510(k) Submitter	510(k) Number
Ultrasonic Bipolar Generator USG-410 with accessories	Olympus Medical Systems Corporation	K211838

4. Device Description

The THUNDERBEAT Type S Hand Instrument (TB-0520FCS, TB-0535FCS, and TB-0545FCS) is a functional device 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. The TBS is used with a compatible ultrasonic generator and transducer. The hand instruments are available in three (3) lengths: 20cm, 35cm, and 45cm.

The THUNDERBEAT Type S Hand Instrument has a probe and a grasping section at the distal tip of the shaft. The probe section is set inside of the shaft. The grasping section is pivotally connected to the shaft. The probe vibrates at ultrasonic frequencies and acts as an electrode for the HF Bipolar output. The grasping section acts as the other electrode for the HF Bipolar output. A non-medical device torque wrench and a stabilizer are included in the packaging of each instrument.

5. Indications for Use

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.

6. Predicate Comparison

Item	Subject Device	Predicate Device	Comments on Difference
	THUNDERBEAT Type S Hand Instrument	**THUNDERBEAT Type S Hand Instrument**	
Manufacturer	OLYMPUS MEDICAL SYSTEMS CORP.	OLYMPUS MEDICAL SYSTEMS CORP.	Same
Indications for Use	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		Same

	coagulation for sterilization procedures, and should not be used for these procedures.		
Single-Use/Reuse	Single Use	Single Use	Same
Sterilization	Ethylene Oxide	Ethylene Oxide	Same
Working Length (cm)	20, 35, 45	20, 35, 45	Same
Shaft rotation	360 degrees	360 degrees	Same
Grasping force (N)	24.5±2	24.5±2	Same
Compatibility generator	-STMS USG-400 (K172691) -ESG-400 (K203682) -USG-410 (K211838) -ESG-410 (K231777)	-STMS USG-400 (K172691) -ESG-400 (K203682) -USG-410 (K211838)	Similar Compatibility of the THUNDERBEAT Type S was included in the respective cleared electrosurgical generators' 510(k)s.
Mechanism of Cutting	Ultrasonic & High Frequency	Ultrasonic & High Frequency	Same
Frequency	47 kHz	47 kHz	Same
Amplitude	80 µm	80 µm	Same
Rated high-frequency (RF bipolar) voltage	229 Vp	229 Vp	Same

7. **Comparison of Technological Characteristics with the Predicate Device**
   Compared to the predicate device, the change to the subject device is limited to a design change to the jaw at the distal end of the device. These dimensional changes to the jaw subcomponents do not impact the final device design or specifications as compared to the predicate device. The jaw design change has been shown to be substantially equivalent to the predicate device through comparative bench testing. The 510(k) also included a list of non-reportable (documentation/Letter to File) changes made since the time of last clearance (K211838).

Technological similarities

- The subject device and the predicate device are the same devices

Technological differences

- The jaw design is different between the subject and predicate device. These changes are at the subcomponent level and do not affect the established final device specifications.
- The subject device was the focus of non-reportable changes which caused minor differences between the subject and predicate devices. These changes include documentation, labeling (editorial), manufacturing documentation/equipment, supplier.

The differences in technological characteristics do not impact the safety and effectiveness of the subject device as demonstrated by Performance, Sterilization/Shelf life, EMC, and Biocompatibility testing.

8. Non-Clinical/Clinical Tests Summary and Conclusion

Olympus performed non-clinical testing to demonstrate substantial equivalence to the predicate device. Test samples were final, finished devices subjected to the full manufacturing process including sterilization.

The Mechanical and Durability performance bench tests were conducted to demonstrate substantial equivalence between the subject and predicate devices. All test samples passed pre-defined acceptance criteria.

Sterilization and Shelf-Life

Sterilization and shelf-life testing were conducted according to the recommendations in FDA Guidance Document, Submission and Review of Sterility Information in Premarket Notifications (510(k)) Submissions for Devices Labeled as Sterile, Issued January 8, 2024, as well as the following standards.

- ISO 11135: 2014
- ISO 10993-7: 2008 [Including: ISO 10993-7:2008/COR 1:2009 and ISO 10993-7:2008/AMD 1:2019]
- ASTM F1980-21
- ISO 11607-1: 2019
- ISO 11607-2: 2019

Biocompatibility

The biocompatibility evaluation was conducted in accordance with the FDA Guidance Use of International Standard ISO 10993-1, “Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process”. The subject device is considered an external communicating device (tissue/bone/dentin) contacting for a duration of less than 24 hours.

The testing included the following tests:
- Cytotoxicity
- Sensitization
- Irritation
- Acute Systemic toxicity
- Material Mediated Pyrogenicity

EMC and Electrical Safety
Electrical safety and EMC performance testing was conducted in accordance with the FDA Guidance Electromagnetic Compatibility (EMC) of Medical Devices, Guidance for Industry and Food and Drug Administration Staff, issued on June 6, 2022. The subject device is confirmed to comply with the relevant requirements as noted below.
- ANSI AAMI ES 60601-1:2005+A1:2012+A2:2020
- IEC 60601-1-2:2014+A1:2021
- IEC TR 60601-4-2:2016

9. Conclusion

Based on the comparison to the predicate device, intended use, technological characteristics, and performance testing, the THUNDERBEAT Type S Hand Instrument raises no new issues of safety and effectiveness and is substantially equivalent to the predicate device in terms of safety, efficacy, and performance.