



Food and Drug Administration
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Silver Spring, MD 20993-0002

February 26, 2016

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

Re: K151743

Trade/Device Name: Thunderbeat Open Fine Jaw
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical cutting and coagulation device and accessories
Regulatory Class: Class II
Product Code: GEI, LFL
Dated: January 26, 2016
Received: January 27, 2016

Dear Mr. Baillie:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

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

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in

the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to

<http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,


Jennifer R. Stevenson -A

For Binita S. Ashar, M.D., M.B.A., F.A.C.S.
Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known)
K151743

Device Name
THUNDERBEAT Open Fine Jaw TB-0009OF

Indications for Use (Describe)

The THUNDERBEAT Open Fine Jaw hand instrument is intended to be used with the Ultrasonic Generator (USG-400), the Electrosurgical Generator (ESG-400), and the THUNDERBEAT Transducer, (TD-TB400).

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.

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
Gyrus ACMI, Inc.
THUNDERBEAT Open Fine Jaw TB-0009OF

General Information

Applicant: OLYMPUS MEDICAL SYSTEMS
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Establishment Registration Number: 8010047

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Establishment Registration Number: 9614641

510(k) Submitter: Gyrus ACMI, Inc.
136 Turnpike Rd.
Southborough, MA 01772-2104

Establishment Registration Number: 3003790304

Contact Person: Graham Baillie
Manager, Regulatory Affairs

Date Prepared: February 25, 2016

Classification Name: Electrosurgical cutting and coagulation
device and accessories

Regulation Number: 21 CFR 878.4400

Regulatory Class: Class II,
GEI, LFL

Product Codes: GEI, LFL

Review Panel: General & Plastic Surgery

Trade Name: THUNDERBEAT Open Fine Jaw Hand
Instrument

Generic/Common Name: Ultrasonic and electrosurgical devices

THUNDERBEAT Open Fine Jaw Hand Instrument
Gyrus ACMI, Inc.

Traditional 510(k) Notification
Feb 25, 2016

Model Name	Device Name
TB-0009OF	THUNDERBEAT Open Fine Jaw

Predicate Devices

Olympus Medical Systems Corp. THUNDERBEAT TB-0510IC/0520IC	K132703
Covidien LigaSure Small Jaw	K113572
Ethicon Harmonic Focus	K100597

Device Description

The THUNDERBEAT Open Fine Jaw TB-0009OF is intended to be used with the Ultrasonic Generator (USG-400), the Electrosurgical Generator (ESG-400), and the THUNDERBEAT Transducer, (TD-TB400).

The THUNDERBEAT Open Fine Jaw TB-0009OF is provided as a sterile, single use device. It is a functional device capable of vessel sealing & cutting, tissue coagulating & cutting, grasping, and dissecting. This device has been designed to seal and cut vessels up to and including 7 mm in diameter, tissue bundles, and lymphatics for open, open ENT procedures in surgery.

Technological Characteristics

The THUNDERBEAT Open Fine Jaw TB-0009OF has two different output modes:

- Seal and Cut mode: Activating the Ultrasonic output (generated by the USG-400, Ultrasonic Generator) and the HF Bipolar output (generated by the ESG-400) simultaneously enables sealing and cutting of vessels, tissue bundles, and lymphatics and cutting and coagulation soft tissue.
- Seal mode: Uses only the HF Bipolar (ESG-400) energy output which enables vessel, tissue bundle and lymphatic sealing and hemostasis.

Intended Use

The THUNDERBEAT Open Fine Jaw hand instrument is intended to be used with the Ultrasonic Generator (USG-400), the Electrosurgical Generator (ESG-400), and the THUNDERBEAT Transducer, (TD-TB400).

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.

Comparison of Technological Characteristics

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

Feature		Proposed THUNDERBEAT Open Fine Jaw TB-0009OF		Predicate THUNDERBEAT TB-0510IC/0520IC (K132073)		Predicate LigaSure Small Jaw K113572	Predicate Harmonic Focus K100597
Instrument working length		9cm		10, 20cm		Unknown	9cm
Shaft rotation		No rotation		360 degrees		No rotation	No rotation
Output mode		Seal and Cut mode Combined output (Ultrasonic and HF Bipolar)	Seal mode HF Bipolar	Seal and Cut mode Combined output (Ultrasonic and HF Bipolar)	Seal mode (HF Bipolar)	HF Bipolar	Ultrasonic
Ultrasonic output	Ultrasonic Output Frequency	47kHz	Not activated	47kHz	Not activated	Not activated	55kHz
	Probe Amplitude	64µm	Not activated	80µm	Not activated	Not activated	Unknown
HF Bipolar output		Activated	Activated	Activated	Activated	Activated	Not activated
Tissue or vessel cutting mechanism		ultrasonic vibration	No cutting	ultrasonic vibration	No cutting	A mechanical blade deploys	Ultrasonic vibration
Shaft Diameter		No shaft	No shaft	5.5mm	5.5mm	No shaft	No shaft
Handle		hemostat-style body		Inline Grip with shaft body		hemostat-style body	hemostat-style body

Compliance to Voluntary Standards

The design of the THUNDERBEAT Open Fine Jaw TB-0009OF complies with the following standards:

- IEC60601-1: 2005+A1 Medical electrical equipment – Part1: General Requirements for basic safety and essential performance
- IEC60601-1-2 Edition 3: 2007-03 Medical electrical equipment – Part 1-2; General requirements for basic safety and essential performance – Collateral Standard: Electromagnetic disturbances – Requirement and tests
- AAMI ANSI IEC60601-2-2:2009 Medical electrical equipment. Particular requirements for the basic safety and essential performance of high frequency surgical equipment and high frequency surgical accessories
- ISO10993-1: Forth Edition 2009-10-15 Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process
- AAMI ANSI ISO10993-5: 2009/(R) 2014 Biological evaluation of medical devices – Part5: Tests for in vitro cytotoxicity
- ISO10993-7 Second Edition: 2008-10-15 Biological evaluation of medical devices – Part 7: Ethylene oxide sterilization residuals
- AAMI ANSI ISO10993-10: 2010 Biological evaluation of medical devices. Tests for irritation and sensitization
- ISO10993-11 Second Edition: 2006-08-15 Biological evaluation of medical devices. Tests for systemic toxicity
- ISO11135-1:2007 Sterilization of health-care products – ethylene oxide – Requirements for the development, validation and routine control of a sterilization process for medical devices
- ISO14971 Second Edition: 2007-03-01 – Medical devices - Application of risk management to medical devices
- ASTM F1980-07(Reapproved 2011) Standard Guide for Accelerated Aging of Sterile Barrier Systems for Medical devices

Summary of Non-clinical Testing

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

Sterilization has been tested to comply with ISO11135-1: 2007.

Accelerated Aging testing confirmed that the subject device has a three year shelf life.

Bench Testing

Test Code	Title	Objective
#A1	THUNDERBEAT Open Fine Jaw Ex-vivo Sealing & Cutting and Sealing Performances Confirmation Test on Blood Vessels	This test was designed to confirm the sealing & cutting and sealing performances of THUNDERBEAT Open Fine Jaw
#A2	THUNDERBEAT Open Fine Jaw Ex-vivo Sealing & Cutting Performance - Comparative Test on Blood Vessels	This test was designed to compare the sealing & cutting performance of the THUNDERBEAT Open Fine Jaw with the conventional bipolar device
#B1	THUNDERBEAT Open Fine Jaw Ex-vivo Cutting Performance Comparative Test on Mesentery.	This test was designed to compare the cutting performance of THUNDERBEAT Open Fine Jaw with those of THUNDERBEAT, conventional bipolar and ultrasonic devices
#Fb1	Sealing performance and characteristics of the THUNDERBEAT Open Fine Jaw SEAL & CUT mode during activation.	This test was designed to verify the sealing performance and characteristics of THUNDERBEAT Open Fine Jaw during SEAL&CUT mode output compared with a conventional ultrasonic device
#Fb2	Cutting performance and characteristics of the THUNDERBEAT Open Fine Jaw SEAL & CUT mode during activation.	This test was designed to verify the characteristics of THUNDERBEAT Open Fine Jaw during SEAL&CUT mode output compared with a conventional ultrasonic device
#H	Comparison of grasping and dissection performance between the THUNDERBEAT Open Fine Jaw and the control devices.	This test was designed to confirm grasping and dissection performance of the THUNDERBEAT Open Fine Jaw by comparison with the control devices
#I/J	THUNDERBEAT Open Fine Jaw Maximum Temperature and Cooling Time of the Grasping Section.	This test was designed to compare maximum temperature and cooling time of the grasping section of the THUNDERBEAT Open Fine Jaw and the control devices
#L	THUNDERBEAT Open Fine Jaw Grasping force distribution verification report on wiper jaw	The purpose of this test is to compare subject device to predicate device regarding evenness of grasping force across grasping section.

Animal Testing:

Canine animal model was used for performance testing M and G, and porcine animal models were used for performance testing Ca and D.

Test Code	Title	Objective
#D	THUNDERBEAT Open Fine Jaw Performance and Safety Confirmation Test on Blood Vessels, Lymphatics and Tissue Bundle (Acute Animal Testing)	This test was designed to confirm the performance of THUNDERBEAT Open Fine Jaw on blood vessels up to 7.0 mm in diameter, lymphatics and tissue bundles, and its safety on blood vessels up to 7.0 mm in diameter and tissue bundles with blood vessels and lymphatics by comparing the seal achievement rate, thermal spread, degree of degeneration and seal achievement with those yielded
#Ca	THUNDERBEAT Open Fine Jaw Performance Confirmation Test on Blood Vessels, Lymphatics and Tissue Bundles (Chronic Animal Testing)	This test was designed to confirm the performance of THUNDERBEAT Open Fine Jaw on blood vessels up to 7.0 mm in diameter, lymphatics and tissue bundles by comparing the seal achievement and maintenance rates with those yielded
#G	THUNDERBEAT Open Fine Jaw Safety and Performance Confirmation Test on ENT Procedures (Chronic Animal Testing)	This test was designed to confirm the safety and performance of THUNDERBEAT Open Fine Jaw when utilized during ENT procedures including thyroidectomy, parathyroidectomy, parotidectomy, and tonsillectomy
#M	THUNDERBEAT Open Fine Jaw Safety and Performance Confirmation Test on ENT Procedures (Acute Animal Testing)	This test was designed to confirm the safety and performance of THUNDERBEAT Open Fine Jaw when utilized during ENT procedures including thyroidectomy, parathyroidectomy, parotidectomy, and tonsillectomy. The thermal spread and the acute tissue response of the THUNDERBEAT Open Fine Jaw on the usage in the ENT procedures were evaluated in comparison with the control devices

Summary of Clinical Testing

Clinical testing using the subject device itself was not conducted. Therefore, a clinical meta-analysis that considered the safety and effectiveness of predicate devices being used in the same procedures proposed for the subject device was conducted.

Conclusion:

Performance tests summarized above demonstrated that the Gyrus ACMI THUNDERBEAT Open Fine Jaw TB-0009OF is substantially equivalent to the predicate devices and presents no new questions of safety or efficacy.