May 11, 2020

Olympus Medical Systems Corp.
Christina Flores
Manager, Regulatory Affairs
Gyrus ACMI inc.
136 Turnpike Road
Southborough, Massachusetts 01772

Re: K192103
Trade/Device Name: Thunderbeat Open Fine Jaw Type X Hand Instrument
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical cutting and coagulation device and accessories
Regulatory Class: Class II
Product Code: GEI, LFL
Dated: May 6, 2020
Received: May 7, 2020

Dear Christina Flores:

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,

for Michael J. Ryan
Director
DHT1C: Division of ENT, Sleep Disordered Breathing, Respiratory and Anesthesia Devices
OHT1: Office of Ophthalmic, Anesthesia, Respiratory, ENT and Dental 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K192103

Device Name
THUNDERBEAT Open Fine Jaw Type X hand instrument

Indications for Use *(Describe)*
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.

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 Type X hand instrument

General Information

Applicant:	OLYMPUS MEDICAL SYSTEMS CORP. 2951 Ishikawa-cho, Hachioji-shi, Tokyo, Japan 192-8507 Phone: (+81) 42-642-2694 Fax: (+81) 42-642-2307
Establishment Registration Number:	8010047
Manufacturer:	Aomori Olympus 2-248-1 okkonoki kuroishi-shi aomori, Japan 036-0357 Phone: (+81) 172-52-8543 Fax: (+81) 172-52-8515
Establishment Registration Number:	9614641
510(k) Submitter:	Gyrus ACMI, Inc. 136 Turnpike Rd. Southborough, MA 01772-2104
Establishment Registration Number:	3003790304
Contact Person:	Christina Flores, RAC Manager, Regulatory Affairs
Date Prepared:	May 10, 2020

Device Description

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

Trade Name: THUNDERBEAT Open Fine Jaw Type X hand instrument

Model Name	Device Name
TB-0009OFX	THUNDERBEAT Open Fine Jaw Type X hand instrument

Generic/Common Name: Ultrasonic and electrosurgical devices

Primary Predicate Device

Device name	510(k) Submitter	510(k) No.
THUNDERBEAT Open Fine Jaw (TB-0009OF)	OLYMPUS MEDICAL SYSTEMS CORP.	K151743

Secondary Predicate Device

Device name	510(k) Submitter	510(k) No.
LigaSure Curved, Small Jaw, Open Sealer/Divider	COVIDIEN	K113572

Product Description

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

The THUNDERBEAT Open Fine Jaw Type X hand instrument is provided as a sterile, single use device. The subject device is 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. This device also has been designed for open ENT procedures in adults.

Comparison of Technological Characteristics

The basic principle and operational characteristics of the subject device are identical to the predicate device. The proposed THUNDERBEAT Open Fine Jaw Type X Hand Instrument is equivalent to the predicate device in that each device is connected to Surgical Tissue Management System, specifically the ESG-400 Electrosurgical Generator, USG-400 Ultrasonic Generator and THUNDERBEAT Transducer (TD-TB400). Like the predicate device, the subject device activates combined HF Bipolar (FineCoag) output and Ultrasonic output [Seal & Cut mode] simultaneously or only the HF Bipolar output (Seal mode) while grasping vessels, tissue bundles and lymphatics between the Probe and the H electrode in the Grasping section.

In terms of the design concept of the subject device, the differences from the predicate device are as follows:

- Addition of the Radical Neck Dissection indication
- Removal of generator specific information from indications for use
- Adding resin cover (PEEK) on the H electrode
- Changing a material of H electrode in the grasping section and Sheath cover

A side by side comparison of the subject device and the predicate device is provided below.

Item	Subject Device	Primary Predicate Device (PD) K151743	Secondary Predicate Device (PD2) K113572	Discussion
	TB-0009OFX	TB-0009OF	LigaSure Curved, Small Jaw, Open Sealer/Divider	
Indications for Use	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,	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.	The LigaSure™ Curved, Small Jaw, Open Sealer / Divider is a bipolar electrosurgical instrument intended to be used with the ForceTriad™ energy platform. The instrument is indicated for use in open general surgical procedures where ligation and division of vessels (up to 7 mm in diameter), tissue bundles, and lymphatics is performed, such as urologic, thoracic, plastic, and reconstructive, and including such procedures as bowel resections, gall bladder procedures, Nissen fundoplication, adhesiolysis, etc. The device is also indicated for open ENT procedures in adults	The differences between SD and PD are the removal of the specific generator information and the addition of the Radical Neck Dissection indication. The Radical Neck Dissection indication is carried by the PD2.

Item	Subject Device	Primary Predicate Device (PD) K151743	Secondary Predicate Device (PD2) K113572	Discussion
	TB-0009OFX	TB-0009OF	LigaSure Curved, Small Jaw, Open Sealer/Divider	
	parathyroidectomy, parotidectomy, radical neck dissection, and tonsillectomy) for only ligation (sealing and cutting) of vessels, lymphatics and tissue bundles greater than 3mm 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 3mm away from	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 2-3 mm*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,	(thyroidectomy, radical neck dissection, parotidectomy, and tonsillectomy) for ligation and division of vessels, lymphatics and tissue bundles 2-3 mm away from unintended thermally sensitive structures such as nerves and parathyroid glands. The LigaSure system has not been shown to be effective for tubal sterilization or tubal coagulation for sterilization procedures. Do not use the LigaSure system for these procedures.	

Item	Subject Device	Primary Predicate Device (PD) K151743	Secondary Predicate Device (PD2) K113572	Discussion
	TB-0009OFX	TB-0009OF	LigaSure Curved, Small Jaw, Open Sealer/Divider	
	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.	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.		
Regulation Number	878.4400	878.4400	878.4400	Same as PD
Regulation Name	Electrosurgical, cutting & coagulation & accessories	Electrosurgical, cutting & coagulation & accessories	Electrosurgical, cutting & coagulation & accessories	
Regulatory Class	II	II	II	
Product Code	GEI, LFL	GEI, LFL	GEI	
Classification Panel	General & Plastic Surgery	General & Plastic Surgery	General & Plastic Surgery	
Basic principle	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	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	High-frequency current generated by Covidien's Electrosurgical Generators (such as Force Triad) is delivered to the jaw (electrodes), and coagulate (seal) vessels,	Same as PD

Item	Subject Device	Primary Predicate Device (PD) K151743	Secondary Predicate Device (PD2) K113572	Discussion
	TB-0009OFX	TB-0009OF	LigaSure Curved, Small Jaw, Open Sealer/Divider	
	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.	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.	tissue bundles, lymphatics clamped by the jaw. The internal mechanical blade in the jaw makes the soft tissues divided	
Handle shape	hemostat-style body	hemostat-style body	hemostat-style body	Same as PD
Tip shape	Probe and H electrode	Probe and H electrode	Jaw	Same as PD
Resin cover on the tip of grasping section	Equipped	N/A	Unknown	The resin cover is added on the H electrode.
Grasping section	PTFE/SUS630	PTFE/Aluminum alloy	SUS	The material of the H electrode was changed from aluminum alloy to SUS63.
Device performance	Performance testing including Bench and Animal testing was conducted in support of the substantial equivalence determination.			
Reprocessing	Sterile, for single use	Sterile, for single use	Sterile, for single use	Same as PD
Shelf Life	3years	3years	Unknown	Same as PD

Item	Subject Device	Primary Predicate Device (PD) K151743	Secondary Predicate Device (PD2) K113572	Discussion
	TB-0009OFX	TB-0009OF	LigaSure Curved, Small Jaw, Open Sealer/Divider	
Patient Contacting Materials	Poly-carbonate, ADC12, PEEK, PTFE, SUS630, PTFE composite nickel plating, SUS304, SUS303, Ti-6A1-4V	Poly-carbonate, ADC12, Zircon oxide, PFA, PTFE, Aluminum alloy (A7075-T6), PTFE, composite nickel plating, Parylene HT (tetrafluoro-di- para-xylylene), Aluminum alloy (ADC12), Zircon oxide (inside), SUS303, Ti-6A1-4V	SUS Other materials are unknown.	Biological safety of the material was tested in accordance with ISO10993.

Material

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

Indications for use

The THUNDERBEAT 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 3mm 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 3mm 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.

Compliance to Voluntary Standards

The design of the THUNDERBEAT Open Fine Jaw Hand Instrument complies with the following standards:

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

Device-specific guidance

- Premarket Notification (510(k)) Submissions for Bipolar Electrosurgical Vessel Sealers for General Surgery - Guidance for Industry and Food and Drug Administration Staff, 08/15/2016
- Premarket Notification (510(k)) Submissions for Electrosurgical Devices for General Surgery - Guidance for Industry and Food and Drug Administration Staff, 08/15/2016

Summary of Sterilization and Shelf Life Discussion

Sterilization testing for the THUNDERBEAT Open Fine Jaw Type X hand instrument was conducted in accordance with the FDA's Guidance for Industry and Food and Drug Administration Staff, "Submission and Review of Sterility Information in Premarket Notification (510(k)) Submissions for Devices Labeled as Sterile". Stability evaluation for the sterile packaging and for product performance supports the three year shelf life. Accelerated aging test was conducted in accordance with ASTM F1980-16, the standard guide for accelerated aging of sterile barrier systems for medical devices.

Summary of Performance Testing

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

1. Bench Testing

Test Code	Item	Contents
OFJX-001	*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.
OFJX-020	Ex Vivo Testing for Temperature-time History	Ex Vivo Testing for Temperature-time History was conducted on both the subject and predicate devices compare the spatio-temporal temperature distribution and thermal damage.

2. Animal Test

Test Code	Item	Contents
OFJX-012 OFJX-014 OFJX-015	Chronic Animal Study	Chronic animal study of porcine/ Beagle Dogs 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).
OFJX-011-a OFJX-013 OFJX- 018b OFJX-016	Acute Animal Study	Acute animal study of porcine/ Beagle Dogs was conducted on both the subject and predicate devices to demonstrate seal performance and safety (ex. seal maintenance rates include vessels up to 7.0mm in diameter and lymphatics and tissue bundles, thermal spread, degree of degeneration).

3. Clinical Testing

Clinical testing was not performed.

Substantial Equivalence

The subject and predicate device have the same fundamental technology. Compared with the primary predicate device (K151743), the subject device proposes the expanded indication of Radical Neck Dissection; the removal of generator specific information from indications for use; a design modification that includes a resin cover (PEEK) addition on the electrode; and the material change of H electrode and Sheath cover. The secondary predicate device (K113572) is being used for the expanded indication of Radical Neck Dissection. To support the proposed modifications, the performance tests summarized above were conducted.

Conclusion

In summary, the THUNDERBEAT Open Fine Jaw Type X hand instrument is substantially equivalent to the predicate device and presents no new questions of safety or effectiveness.