

JAN 20 2012

**510(k) SUMMARY**

Surgical Tissue Management System  
Ultrasonic surgical system

January 20, 2012

**1 General Information**

- Applicant: OLYMPUS MEDICAL SYSTEMS CORP.  
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Establishment Registration No: 8010047
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Regulatory Affairs & Quality Assurance  
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- Manufacturer: Aomori Olympus Co., Ltd.  
248-1 Okkonoki 2-chome Kuroishi-shi,  
Aomori, Japan 036-0367  
Establishment Registration No.: 9614641

**2 Device Identification**

- Device Trade Name: Surgical Tissue Management System
- Common Name: Ultrasonic surgical system
- Regulation Number: 21 CFR 878.4400  
21 CFR 876.4300  
Unclassified
- Regulation Name: Electrosurgical, cutting & coagulation device and accessories  
Endoscopic electrosurgical unit and accessories  
Instrument, Ultrasonic surgical
- Regulatory Class: II
- Classification Panel: General and Plastic Surgery, Gastroenterology/ Urology
- Product Code: GEI, KNS, LFL

### **3 Predicate Device Information**

**Table 12-1 Primary Components & Predicate Devices of the Surgical Tissue Management System**

<b>Subject Device (Part of this submission)</b>	<b>Predicate Device</b>	<b>PD's 510(k) No.</b>
Ultrasonic Generator USG-400 Electrosurgical Generator ESG-400	Olympus Ultrasonic Surgical System Sonosurg	K050885
	UltraCision Harmonic Scalpel Generator 300 System	K002906
	Valleylab ForceTriad Eleotrosurgical Generator	K051644
	Valleylab ForceTriad Eleotrosurgical Generator	K070162
	EnSeal Vessel Sealing & Hemostasis System (with RF-60 generator/controller)	K043008
THUNDERBEAT TRANSDUCER TD-TB400 SONICBEAT TRANSDUCER TD-SB400	Olympus Ultrasonic Surgical System	K021962
	Olympus Ultrasonic Surgical System	K031305
	Olympus Ultrasonic Sonosurg System	K031523
	Olympus Ultrasonic Surgical System	K031710
	Olympus Ultrasonic Surgical System Sonosurg	K050885
	Ultrasonic Harmonic Scalpel Hand Piece	K990430
	UltraCision Harmonic Scalpel Generator 300 System	K002906
THUNDERBEAT TB-0545PC/ 0535PC/ 0545IC/ 0535IC/ 0520IC/ 0510IC SONICBEAT SB-0545PC/ 0535PC/ 0545IC/ 0535IC/ 0520IC/ 0510IC	Olympus Ultrasonic Surgical System	K021962
	Olympus Ultrasonic Surgical System	K031305
	Olympus Ultrasonic Sonosurg System	K031523
	Olympus Ultrasonic Surgical System	K031710
	Olympus Ultrasonic Surgical System Sonosurg	K050885
	Ligasure 5mm Laparoscopic Sealer-Divider, Model LS1500	K031011
	Harmonic ACE Curved Shears with Pistol Handle and Hand Control and Harmonic ACE Curved Shears with Scissor Handle and Hand Control	K051036
	EnSeal PowerTip with EnSeal Universal	K081129
	EnSeal Vessel Sealing & Hemostasis System	K031133

### **4 Device Description**

The Surgical tissue management system has been designed to be used for open, laparoscopic, and endoscopic procedures in surgery. With the Ultrasonic Generator (USG-400) as the main component, the system is composed of the Electrosurgical Generator (ESG-400, K103032), the THUNDERBEAT (TB-0545PC, 0535PC, 0545IC, 0535IC, 0520IC, 0510IC), the SONICBEAT (SB-0545PC, 0535PC, 0545IC, 0535IC, 0520IC, 0510IC), and the Transducer (TD-TB400, TD-SB400).

### Output mode

The Surgical tissue management system has three different output modes.

- Seal & Cut mode (when a THUNDERBEAT and THUNDERBEAT TRANSDUCER are connected with the system):

Combining and activating the Ultrasonic output and the HF Bipolar output simultaneously enables to seal and cut vessels and to cut and coagulate soft tissue.

- Seal mode (when a THUNDERBEAT and THUNDERBEAT TRANSDUCER are connected with the system):

Activating the HF Bipolar output enables vessel sealing and hemostasis.

- Ultrasonic mode (when a SONICBEAT and SONICBEAT TRANSDUCER are connected with the system)

Activating the Ultrasonic output enables to seal and cut vessels and to cut and coagulate soft tissue.

### Output

- To use the THUNDERBEAT, the handpiece plug of the THUNDERBEAT Transducer which converts drive current into Ultrasonic output is connected to the THUNDERBEAT socket of the USG-400. Then HF Bipolar current and drive current are supplied to the Transducer via a cable, eliminating the need to connect a cord to the ESG-400.

- To use the THUNDERBEAT, the centralized control function of the USG-400 controls the HF Bipolar output and the output settings of the ESG-400. In other words, operating the Handswitches mounted on the THUNDERBEAT enables to turn ON/OFF the Seal & Cut mode output and the Seal mode output. Operating the Touch-screen of the USG-400 facilitates changing the output settings.

- To use the SONICBEAT, the handpiece plug of the SONICBEAT Transducer is connected to the SONICBEAT socket of the USG-400. Operating either of the Handswitches of the SONICBEAT enables to ON/OFF the Ultrasonic output.

## **5 Indications for Use**

### Surgical Tissue Management System

The Surgical Tissue Management System is intended to be used with the Ultrasonic Generator (USG-400), the Electrosurgical Generator (ESG-400), the THUNDERBEAT Transducer (TD-TB400), the SONICBEAT Transducer (TD-SB400), the THUNDERBEAT, and / 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 Surgical Tissue Management System has three output modes, Seal & Cut (THUNDERBEAT), Seal (THUNDERBEAT) and Ultrasonic (SONICBEAT). The Seal & Cut mode provides combined HF bipolar and ultrasonic energy, the seal mode provides only HF bipolar energy and the Ultrasonic mode provides only ultrasonic energy.

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

#### Ultrasonic Generator (USG-400)

The Ultrasonic Generator (USG-400) is intended to be used with the Electrosurgical Generator (ESG-400), the THUNDERBEAT Transducer (TD-TB400), the SONICBEAT Transducer (TD-SB400), the THUNDERBEAT, and / 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.

#### Electrosurgical Generator (ESG-400 K103032)

The ESG-400 is an electrosurgical generator intended for tissue cutting and coagulation in open, laparoscopic and endoscopic surgery in conjunction with electrosurgical accessories and ancillary equipment.

#### THUNDERBEAT Transducer (TD-TB400)

The THUNDERBEAT Transducer (TD-TB400) is intended to be used with the Ultrasonic Generator (USG-400), the Electrosurgical Generator (ESG-400), and the THUNDERBEAT for open, laparoscopic (including single-site surgery), and endoscopic surgery to cut (dissect) or coagulate soft tissue or to ligate (seal and cut) vessels.

#### THUNDERBEAT (TB-0545PC, 0535PC, 0545IC, 0535IC, 0520IC, 0510IC)

The THUNDERBEAT hand instruments are 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 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 7mm in diameter.

##### Seal mode:

The THUNDERBEAT 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 7mm in diameter.

The THUNDERBEAT 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.

#### SONICBEAT Transducer (TD-SB400)

The SONICBEAT Transducer (TD-SB400) is intended to be used with the Ultrasonic Generator (USG-400) and 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.

#### SONICBEAT (SB-0545PC, 0535PC, 0545IC, 0535IC, 0520IC, 0510IC)

The SONICBEAT is intended to be used with the Ultrasonic Generator (USG-400) and the SONICBEAT Transducer (TD-SB400) 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.

### **6 Comparison of Technological Characteristics**

The Surgical Tissue Management System is basically identical to the predicate device in intended use, and similar in specifications.

#### Generator:

When compared to the predicate electrical surgical generators, the subject device has the similar technological features such as the number of instruments sockets, footswitch options, output, output levels and waveforms. There are differences in the input current, RF bipolar frequency, RF bipolar constant voltage and maximum wattage, however these differences are considered minor and do not impact the performance of the device as demonstrated in performance testing.

When compared to the predicate ultrasonic generators, the subject device has the similar technological features such as the footswitch options, output, frequency output, output levels and waveforms. The Input current, ultrasonic output voltage and ultrasonic output current are different, however these differences are considered minor and do not impact the performance of the device as demonstrated in performance testing.

#### Instruments:

When compared to the predicate electrical surgical instruments (K031011 and K081129), the subject device THUNDERBEAT instruments has similar technological features such as the shaft length, shaft rotation, shaft diameter and vessel seal claim. The only difference is that the subject device does not require a mechanical blade for cutting.

When compared to the predicate ultrasonic instruments (K050885 and K051036), the subject device has similar technological features such as the shaft length, shaft rotation, shaft diameter, cutting mechanism and vessel seal claim.

## **7 Substantially Equivalent Discussion**

The Surgical Tissue Management System subject device is a modification to an Ultrasonic Generator to allow for independent or synchronistic use with a previously cleared Electrosurgical Unit (ESG400, K103032). The indications for use, principles of operation and fundamental technology of the Surgical Tissue Management System are similar to the predicate devices. The indicated patient population and procedures are also similar or identical to the predicate devices.

The main difference between the predicate devices and the Surgical Tissue Management System is that in the THUNDERBEAT Seal & Cut mode, ultrasonic and HF bipolar energy are combined to seal and cut tissue. The predicate devices use either HF bipolar or ultrasonic energy to seal and/or cut vessels. The combined energy output has been verified and validated to be equivalent in sealing performance, thermal spread and coagulation (ex vivo burst pressure tests and in vivo animal acute and survival study, hemostasis), when compared to the predicate devices with the same indications. As the performance test results demonstrate equivalent performance, we believe there are no new concerns regarding safety or efficacy as it relates to combining HF bipolar and ultrasonic energy for vessel sealing and cutting.

The THUNDERBEAT and SONICBEAT handpiece series are similar in method of operation and design as the predicate devices. In addition, similar or identical materials are used and biocompatibility results were provided.

## **8 Summary of Non-Clinical Testing**

The following non-clinical test, preclinical test, and usability studies were performed:

### **Non-Clinical/ Preclinical Performance**

Evidence of safety and effectiveness was obtained from two primary areas:

- (1) non-clinical (electrical/mechanical/functional/biocompatibility/stability) performance testing
- (2) preclinical (bench tissue/animal) evaluations and testing

Non-clinical: Basic safety and performance testing was performed in accordance with IEC 60601-1, IEC60601-1-1, 60601-1-2, and IEC60601-2-2. In addition, verification and comparison studies were conducted to evaluate the mechanical and functional performance. Specifically, test results in the following areas were provided: temperature of the grasping

section, less mist production, dissecting performance, wiper jaw technology performance(grasping force).

#### Biocompatibility

- In Vitro Cytotoxicity Test
- Skin Sensitization Test
- Intracutaneous Reactivity Test
- Acute Systemic Toxicity Test

#### Stability

Representative samples of devices were subjected to accelerated and real time ageing. The results of the accelerated age testing demonstrates that the device will be stable for the stated shelf-life. In addition, real time age testing will confirm the results of the accelerated age testing. The test devices were evaluated to ensure they continued to meet their specifications.

Preclinical: Evidence obtained from preclinical bench tissue (ex vivo) and animal (in vivo acute and chronic) studies using porcine and canine models (and in a variety of tissue types and conditions) demonstrate that the THUNDERBEAT and SONICBEAT performs substantially equivalent to the predicate devices in relevant aspects associated with sealing and cutting tissue; namely,

Evaluated ex vivo using excised porcine carotid, splenic, renal arteries, mesenterium, and jejunum.

- sealing performance (burst pressure) with isolated vessel
- ligation (sealing) speed with isolated vessel
- cutting speed with mesenterium and jejunum

Evaluated in vivo/acute using porcine models

- overall hemostasis (isolated arteries)
- overall cutting speed (mesenterium and peritoneum)
- lateral thermal spread (measured on sealed isolated vessels)

Evaluated in vivo/chronic using canine models

- ability to maintain hemostasis at application and through survival (isolated arteries)
- tissue healing through histological sample
- blood testing

### 3) Use of Standards

The following standards were used during the design and validation of the subject devices:

- a) IEC 60601-1:1988+A1:1991+A2:1995
- b) IEC60601-1-1:2000
- c) IEC60601-2-2:2006
- d) IEC 60601-1-2:2001+A1:2004
- e) ISO10993-1:2003
- f) ISO10993-5:2009
- g) ISO10993-10:2002

- h) ISO10993-11:2006
- i) AAMI/ANSI/ISO17665-1:2006
- j) AAMI/ANSI/ISO11135:2007
- k) ASTM F1980-07
- l) ISO14971:2007

The risk analysis was carried out in accordance with established in-house acceptance criteria based on ISO 14971:2007. The design verifications tests and their acceptance criteria were identified and performed as a result of this risk analysis assessment.

## **9 Conclusion**

When compared to the predicate device, the Surgical Tissue Management System does not incorporate any significant changes in intended use, method of operation, material, or design that could affect the safety or effectiveness of the device.





DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
10903 New Hampshire Avenue  
Document Control Room - WO66-G609  
Silver Spring, MD 20993-0002

Olympus Medical Systems Corporation  
% Ms. Stacy A. Kluesner, M.S., RAC  
Regulatory Affairs and Quality Assurance  
3500 Corporate Parkway  
Center Valley, Pennsylvania 18034-0610

JAN 20 2012

Re: K111202

Trade/Device Name: Surgical Tissue Management System  
Regulation Number: 21 CFR 878.4400  
Regulation Name: Electrosurgical cutting and coagulation  
device and accessories

Regulatory Class: Class II  
Product Code: GEI, KNS, LFL

Dated: October 26, 2011

Received: October 31, 2011

Dear Ms. Kluesner:

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

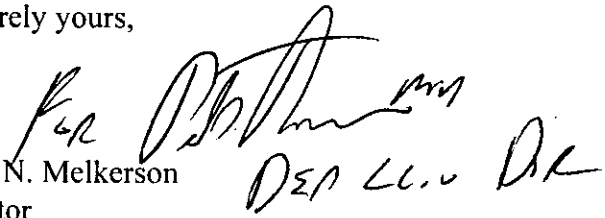
Page 2 – Ms. Stacy A. Kluesner

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 go to for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 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 Small Manufacturers, International and Consumer Assistance 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,

  
Mark N. Melkerson  
Director  
Division of Surgical, Orthopedic  
and Restorative Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

## Indications for Use

510(k) Number (if known): K111202

Device Name: Surgical Tissue Management System

The Surgical Tissue Management System is intended to be used with the Ultrasonic Generator (USG-400), the Electrosurgical Generator (ESG-400), the THUNDERBEAT Transducer (TD-TB400), the SONICBEAT Transducer (TD-SB400), the THUNDERBEAT, and / 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 Surgical Tissue Management System has three output modes, Seal & Cut (THUNDERBEAT), Seal (THUNDERBEAT) and Ultrasonic (SONICBEAT). The Seal & Cut mode provides combined HF bipolar and ultrasonic energy, the seal mode provides only HF bipolar energy and the Ultrasonic mode provides only ultrasonic energy.

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

Nat R. J. [Signature]  
(Division Sign-Off)  
Division of Surgical, Orthopedic,  
and Restorative Devices

510(k) Number K111202

Prescription Use ✓  
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use \_\_\_\_\_  
(21 CFR 807 Subpart C)

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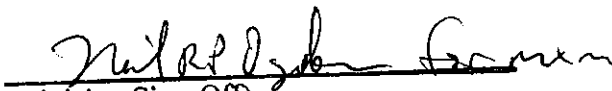
Concurrence of CDRH, Office of Device Evaluation (ODE)

### Indications for Use

510(k) Number (if known): K111202

Device Name: Ultrasonic Generator (USG-400)

The Ultrasonic Generator (USG-400) is intended to be used with the Electrosurgical Generator (ESG-400), the THUNDERBEAT Transducer (TD-TB400), the SONICBEAT Transducer (TD-SB400), the THUNDERBEAT, and / 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.

  
(Division Sign-Off)  
Division of Surgical, Orthopedic,  
and Restorative Devices

510(k) Number K111202

Prescription Use ☒  
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use \_\_\_\_\_  
(21 CFR 807 Subpart C)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

## Indications for Use

510(k) Number (if known): K111202

Device Name:

Electrosurgical Generator (ESG-400 K103032)

The ESG-400 is an electrosurgical generator intended for tissue cutting and coagulation in open, laparoscopic and endoscopic surgery in conjunction with electrosurgical accessories and ancillary equipment.

Neil R. Osborn, M.D.  
(Division Sign-Off)

Division of Surgical, Orthopedic,  
and Restorative Devices

510(k) Number K111202

Prescription Use ✓  
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use \_\_\_\_\_  
(21 CFR 807 Subpart C)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

## Indications for Use

510(k) Number (if known): K111202

Device Name: THUNDERBEAT Transducer (TD-TB400)

The THUNDERBEAT Transducer (TD-TB400) is intended to be used with the Ultrasonic Generator (USG-400), the Electrosurgical Generator (ESG-400), and the THUNDERBEAT 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 Name: THUNDERBEAT (TB-0545PC, 0535PC, 0545IC, 0535IC, 0520IC, 0510IC)

The THUNDERBEAT hand instruments are 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 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 7mm in diameter.

### Seal mode:

The THUNDERBEAT 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 7mm in diameter.

The THUNDERBEAT 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.

Prescription Use ☒   
 (Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use ☐   
 (21 CFR 807 Subpart C)

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Mel R. D. [Signature]  
(Division Sign-Off)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Division of Surgical, Orthopedic,  
and Restorative Devices

510(k) Number K111202

### Indications for Use

510(k) Number (if known): 111202.

Device Name: SONICBEAT Transducer (TD-SB400)

The SONICBEAT Transducer (TD-SB400) is intended to be used with the Ultrasonic Generator (USG-400) and 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 Name: SONICBEAT (SB-0545PC, 0535PC, 0545IC, 0535IC, 0520IC, 0510IC)

The SONICBEAT is intended to be used with the Ultrasonic Generator (USG-400) and the SONICBEAT Transducer (TD-SB400) 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.

W. R. O. J. L. L. L.  
(Division Sign-Off)

### Division of Surgical, Orthopedic, and Restorative Devices

510(k) Number K111202

Prescription Use ✓  
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use \_\_\_\_\_  
(21 CFR 807 Subpart C)

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Concurrence of CDRH, Office of Device Evaluation (ODE)