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510(k) Summary

Date summary prepared: 2/23/2011

510(k) Submitter/Holder
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Name of Device
Trade or Proprietary Name: Sonicision
Common Name: Cordless Ultrasonic Surgical Device
Classification Name: Instrument, ultrasonic surgical (unclassified; product code LFL)

Predicate Devices
The Sonicision Cordless Ultrasonic Dissection Device described in this submission was compared and found to be substantially equivalent to the following ultrasonic surgical devices:

Device Name: Instrument, Ultrasonic, Scalpel
Trade Name [Model Number]: UltraCision Harmonic Scalpel [GEN4; HP054]
510(k) Number: K002906 (cleared 12/15/2000)
Manufacturer: Ethicon Endo-Surgery, Inc.

Device Name: Harmonic ACE Curved Shears with Hand Control
Model Number: ACE36E
510(k) Number: K042777 (cleared 12/1/2004); K060245 (cleared 4/7/2006)
Manufacturer: Ethicon Endo-Surgery, Inc.

Aspects of the system related to the use of a rechargeable lithium battery were compared and found to be substantially equivalent to the use of the battery in the following device:

Device Name: Intelligent Surgical Instrument
Trade Names: i45, i45S, i60, i60S [instruments]; iB100 [battery]; iB1C1 [charger]
510(k) Number: K071708 (cleared 9/27/2007)
Manufacturer: Power Medical Interventions, Inc.

Device Description
The Sonicision™ Cordless Ultrasonic Dissection Device is a hand-held surgical device consisting of three interdependent components that, when assembled, enable ultra high-frequency mechanical motion (ultrasonic energy) to transect, dissect, and coagulate tissue.

The Sonicision device is designed to be both ergonomic and intuitive for the user. It can coagulate vessels up to and including 5 mm in diameter and is designed to be inserted and extracted through a compatible 5 mm trocar, when used endoscopically/laparoscopically. A unique characteristic of the device is that it functions without the need for external power cords and transducer cables.

Sonicision generators and batteries are prepared by the facility and attached to the dissector (disposable component). When assembled, electrical power supplied by the battery pack is available to be converted to ultrasonic energy in the generator. The clinical intended use is achieved by the surgeon when pressure is applied to tissue placed between the clamping jaw and the exposed portion of the probe while activating ultrasonic energy through the use of a two-stage button. The system is comprised of single-use and reusable components, briefly described as follows:

Dissector: The dissector is a sterile, single-use component to which the generator and battery attach. This component contains features essential to the control and performance of the device, such as the clamping jaw, active blade, speaker, energy button, and jaw lever. The shaft measures 39 cm and is designed to function endoscopically through a 5 mm trocar. A rotation wheel enables 360° movement of the shaft.

Torque Wrench: The torque wrench is a sterile, single-use component used to apply the proper amount of torque when attaching the generator to the dissector.

Generator: The generator is a reusable component that attaches to the dissector component. This component contains the transducer, which is used to convert electrical power to ultrasonic energy. Colored light indicators are located on the top of the generator to visually communicate device status information to the user. It is provided non-sterile and must be sterilized prior to each use.

Battery Pack: The battery pack is a reusable component that attaches to the dissector component. This component contains rechargeable lithium-ion polymer cells, which are used to provide electrical power to the generator when charged. A safety valve releases internal pressure in the event of battery damage. The battery pack is provided non-sterile and must be charged and sterilized prior to each use.

Battery Charger: The battery charger is a reusable component designed to charge Sonicision battery packs and communicate battery status information to the user. It contains four charging bays to allow for multi-battery use. Indicator lights located near each charging bay communicate the status of the battery to the user.

Intended Use
The Sonicision™ Cordless Ultrasonic Dissection Device is indicated for soft tissue incisions when bleeding control and minimal thermal injury are desired. The device can be used as an adjunct to or substitute for electrosurgery, lasers, and steel scalpels in general, plastic, pediatric, gynecologic, urologic, exposure to orthopedic structures (such as spine and joint space) and other

open and endoscopic procedures. The Sonicision Cordless Ultrasonic Dissection Device can be used to coagulate isolated vessels up to 5 mm in diameter.

Technological and Performance Characteristics
A detailed comparison of the Sonicision system to the ultrasonic (Harmonic) and battery (Intelligent Surgical Instrument) predicate systems found several technological and performance similarities. The following eight essential relevant similarities were identified and discussed in the submission: (1) basic ultrasonic technology and its fundamental principles, (2) user-operated (manual) control mechanisms, (3) system (automated) control mechanisms, (4) materials, (5) dimensions, shape, and weight, (6) composition and assembly, (7) cordless/battery related aspects, and (8) preclinical performance.

Some technological characteristics were found to be different. Most of the differences are directly attributable to the cordless design of the Sonicision device. Of the differences, six were relevant for discussion in the submission, summarized below. Notably, these differences were found to not affect safety or effectiveness through demonstration of effective performance and equivalency to relevant aspects of the predicate battery-powered device, conformance to industry safety and performance standards, preclinical bench and animal studies, and usability studies.

(1) Cordless design: The predicate ultrasonic devices are not cordless. Differences driven by this design include hand-held device weight and different electrical/mechanical safety and performance risks associated with the use of a lithium-ion polymer battery.

(2) Input power (DC vs. AC): The Sonicision device powers the generator with a rechargeable lithium-ion polymer battery rather than with conventional AC-power.

(3) Sterilization of the generator and battery pack: Sonicision generators and battery packs are sterilized using hydrogen peroxide gas plasma, and are presented aseptically to the sterile field where they are assembled onto the dissector device component. In contrast, the predicate battery pack is not sterilized; rather, it is cleaned and transferred aseptically into the sterile (reusable) instrument with the use of a tool.

(4) Battery pack sterilization: Sonicision battery packs are sterilized using hydrogen peroxide gas plasma, whereas the predicate battery packs are not sterilized, they are cleaned and aseptically transferred to the instrument as described in item #3.

(5) Energy activation button design: The hand activation control mechanism of the Sonicision device is a single two-stage button design, whereas the Harmonic ACE36E device uses two separate single-stage buttons.

(6) Energy level settings: The Sonicision device offers two energy-level settings, whereas the predicate ultrasonic device offers five total energy-level settings through the use of the generator. This difference has a direct impact on active blade displacement. The Sonicision device's amplitude of active blade displacement at the minimum-power mode setting is within the low energy-level setting range of the predicate ultrasonic device, but the Sonicision device's maximum-power mode displacement is higher than the high energy-level setting of the predicate device.

Non-Clinical/Preclinical Performance
Evidence of safety and effectiveness was obtained from three primary areas: (1) non-clinical (electrical/mechanical/ functional) performance testing, (2) preclinical (bench tissue/animal) evaluations and testing, and (3) usability studies.

Non-clinical: Basic safety and performance testing was performed in accordance with IEC 60601-1, IEC 60601-1-2, and IEC 62133. In addition, comparison studies were conducted to evaluate relevant mechanical and functional performance aspects compared to the predicate ultrasonic device; specifically, results in the following areas were provided: active blade displacement, frequency, grasping and pulling force, shaft deflection, distal seal leakage, button activation force, and jaw clamping force (temperature was evaluated during both IEC and preclinical testing).

Preclinical: Information obtained from preclinical bench (in vitro) and animal (in vivo, acute and chronic) studies using porcine demonstrate that the Sonicision Cordless Ultrasonic Dissection Device performs at least as well as (not inferior to) the predicate ultrasonic device (Harmonic ACE36E) in aspects relevant to transecting, dissecting, and coagulating tissue; namely, isolated vessel burst pressures/hemostasis, coagulation and dissection speed, qualitative ratings of the sealed tissue, temperature of the active blade and shaft, thermal spread, and enterotomy formation speed and hemostasis.

Usability: In addition to non-clinical and preclinical testing, usability was evaluated with users in simulated operating environments. These evaluations consisted of formative (verification) and summative (validation) studies, which demonstrate the Sonicision device provides adequate assurance of safety and performance (in regards to human factors/usability aspects) for the patient and operator.

Clinical Performance
This premarket notification report does not rely on the assessment of clinical performance data to demonstrate substantial equivalence.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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FEB 2 4 2011

Re: K101797
Trade/Device Name: Sonicision™ Cordless Ultrasonic Dissection Device
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical cutting and coagulation device and accessories
Regulatory Class: Class II
Product Code: LFL
Dated: February 04, 2011
Received: February 07, 2011

Dear Mr. Horton:

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 go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm 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,

for

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

Enclosure

K101797

Indications for Use Statement

510(k) Number (if known): K101797

Device Name: Sonicision™ Cordless Ultrasonic Dissection Device

Indications for Use:
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Prescription Use ✓ (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Mark A. Ogden for mkn
(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K101797