DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

March 28, 2016

Covidien LLC
Ms. Nancy Sauer
Principal Regulatory Affairs Specialist
5920 Longbow Drive
Boulder, Colorado 80301

Re: K153371
Trade/Device Name: Sonicision Cordless Ultrasonic Dissection Device
Regulation Name: Instrument, Ultrasonic Surgical
Regulatory Class: Unclassified
Product Code: LFL
Dated: February 24, 2016
Received: February 26, 2016

Dear Ms. Sauer:

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 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. 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 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,

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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K153371

Device Name
Sonicision™ Cordless Ultrasonic Dissection Device

Indications for Use *(Describe)*
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.

The Sonicision 13 cm device is also indicated for use in otorhinolaryngologic (ENT) 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 of Safety and Effectiveness

510(k) Number: K153371

Date summary prepared: 03/23/16

510(k) Submitter/Holder

Covidien
5920 Longbow Drive
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Contact

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Regulatory Information

Trade Name:	Sonicision™ Cordless Ultrasonic Dissection Device: • Sonicision Dissector, 13 cm • Sonicision Generator • Sonicision Battery
Common Name:	Ultrasonic Dissection Device
Regulation Number:	NA
Regulation Name:	Instrument, Ultrasonic Surgical
Regulatory Class:	Unclassified
Product Code:	LFL

Predicate Device

The primary predicate device for this submission is the Harmonic FOCUS®+ Shears with Adaptive Tissue Technology (FOCUS+), cleared by 510(k) K133314. The FOCUS+ device is an ultrasonic dissector indicated for use in otorhinolaryngology (ENT) procedures. The Olympus Thunderbeat 0510IC device serves as a reference predicate device (cleared under K132703). The Thunderbeat is a combination ultrasonic/radiofrequency device that has a shaft-based design, similar in size and shape to the Sonicision device assembled with the 13 cm dissector. The Sonicision generator and battery are the same as the designs cleared under 510(k) K101797 and the 13 cm dissector is the same as the design cleared under 510(k) K141371.

Device Description

The Sonicision Ultrasonic Dissection Device that is the subject of this 510(k) is a hand-held battery-powered device used to dissect through tissues and to coagulate vessels up to 5 mm in diameter. An assembled Sonicision device includes three components: (1) The Sonicision Dissector, 13 cm; (2) the Sonicision Battery; and (3) the Sonicision Generator. The dissector is a single-use item that is provided to the user in sterile form. The generator and battery are reusable components that are sterilized by the user. 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 with a button on the handpiece.

Indications for 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.

The Sonicision 13 cm device is also indicated for use in otorhinolaryngologic (ENT) procedures.

Technological Characteristics

Sonicision 13 cm dissector

This is a sterile single-use device that includes the following features:

- Active blade that vibrates at ultrasonic frequency and delivers the energy that provides the tissue effect.
- Clamping jaw that the surgeon uses to provide pressure to vessels, tissues, or vascular bundles as needed to deliver the desired tissue effect.
- Controls for activating the delivery of ultrasonic energy and for opening and closing the clamping jaw.
- Features that interface with the Sonicision generator and the Sonicision battery

Sonicision Generator

This is a reusable component that is sterilized by the user facility using a low-temperature hydrogen peroxide plasma process. It has the following features

- Transducer that converts electrical energy into ultrasonic energy (resonant frequency of approximately 55.5 kHz)
- Indicator LEDs that notify the user of the state of the assembled device
- Control software

Sonicision Battery

This is a reusable component that is sterilized by the user facility using a low-temperature hydrogen peroxide plasma process. It has the following features

- Li-ion chemistry
- 14.8 VDC, rechargeable

Comparison to the Predicate Device

Similarities

- Same intended use and indicated for the same types of surgeries
- Same contraindications
- Same operating principle – a metal waveguide vibrates at ultrasonic frequencies to create thermal and mechanical effects that disrupt cells and tissues. The user can also apply pressure with the passive jaw to achieve specific tissue effects (e.g., coagulating a vessel).
- Same resonant frequency, approx. 55.5 kHz
- Both have two modes of operation: a minimum power mode that is used for vessel coagulation and a maximum power mode that is used for dissection.

Differences

The table below outlines the major differences between the two devices.

Characteristic	Sonicision	FOCUS+
Power source	14.8 VDC Lithium-ion battery	Electrical current delivered through Ethicon Gen11 generator
Instrument form factor	Shaft-based design	Shears-style design
Jaw shape	Straight	Curved
Footswitching option	No	Yes
Audio and Visual Indicators	Visual and audio indicators produced by the hand-held device	Audio and visual indicators produced by the generator.

The impact of these differences was evaluated through:

(1) Comparative studies described below showing equivalent performance of the Sonicision and FOCUS+ devices

(2) Comparison to a reference predicate, the Thunderbeat 0510IC device, a shaft-based device also indicated for use in ENT surgery, which has a similar size and shape to the Sonicision device.

(3) Human factors evaluation of the 13 cm Sonicision Cordless Ultrasonic Dissection Device for use in ENT surgeries, also described below

Performance

Because the Sonicision Cordless Ultrasonic Dissection Device has been previously cleared for use in other types of surgery, the performance testing in this 510(k) focused only on the testing needed to demonstrate suitability of the Sonicision system for otorhinolaryngology (ENT) surgical procedures and substantial equivalence to the predicate device for characteristics deemed relevant for ENT surgical procedures.

- *Ex vivo* burst testing showed that blood vessels coagulated by the Sonicision device had comparable burst strength to the same type of blood vessels coagulated by the FOCUS+ device.
- *Ex vivo* tissue testing showed that the maximum temperature of the Sonicision active blade was comparable to the maximum temperature of the FOCUS+ active blade after multiple activations on mesentery.
- *Ex vivo* tissue testing showed that the maximum temperature of the Sonicision distal shaft was comparable to the maximum temperature of the Thunderbeat distal shaft after multiple activations on mesentery in the ultrasonic mode.
- Acute *in vivo* testing showed that the Sonicision device and the FOCUS+ device achieved comparable rates of hemostasis.
- Usability/ human factors validation in a human cadaver model demonstrated that practicing surgeons could successfully complete representative ENT procedures using the 13 cm Sonicision device. The surgeons, who were predominantly users of the FOCUS+ device for ENT surgeries, found that the 13 cm Sonicision device is clinically acceptable for use in ENT surgical procedures.

Conclusion

The comparison of device characteristics and the review of the performance data support the conclusion that the 13 cm Sonicision Cordless Ultrasonic Dissection Device is substantially equivalent to the Harmonic FOCUS+ Shears with Advanced Tissue Technology device with regard to a general indication for use in otorhinolaryngology (ENT) surgery.