March 26, 2018

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

Re: K180149
Trade/Device Name: Sonicision Reusable Generator, Sonicision Reusable Battery Pack, Sonicision Curved Jaw Dissectors (multiple lengths), Sonicision Battery Charger, Sonicision Battery Insertion Guide
Regulatory Class: Unclassified
Product Code: LFL
Dated: January 18, 2018
Received: January 19, 2018

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.

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.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Jennifer R. Stevenson -S3

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)*
K180149

Device Name
Sonicision Curved Jaw Cordless Ultrasonic Dissection Device

Indications for Use *(Describe)*

The Sonicision™ Curved Jaw 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 and including 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.**

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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# Summary of Safety and Effectiveness

## 510(k) Number:

Date summary prepared: 01/13/2018

### 510(k) Submitter/Holder

Covidien
5920 Longbow Drive
Boulder, CO 80301

### Contact

Nancy Sauer
Regulatory Affairs Manager
Telephone: 303-581-6791
Fax: 303-530-6313
Email: nancy.k.sauer@medtronic.com

### Name of Device

Trade Name: Sonicision™ Curved Jaw Cordless Ultrasonic Dissection Device and Accessories
Common Name: Ultrasonic Dissection Device
Classification Name: None established

### Predicate Device

The primary predicate device for this submission is the Sonicision™ Cordless Ultrasonic Dissection Device family and accessories. The following table identifies the products included in the predicate device family and the most recent 510(k) for each of these products.

| Component Description (Catalog Number) | Applicable 510(k)s |
|---|---|
| Sonicision Reusable Generator (SCG) | K101797<br>K153371 |
| Sonicision Reusable Battery (SCB) | K101797<br>K153371 |
| 39 cm Single use Dissector (SCD39x) | K101797 |
| 13 cm Single use Dissector (SCD13) | K141371<br>K153371 |
| 26 cm Single use Dissector (SCD26) | K141371 |
| 48 cm Single use Dissector (SCD48) | K141371 |
| Sonicision Battery Charger (CBC) | K101797 |
| Sonicision Torque Wrench (SCT12) | K101797 |

The i-Drive Powered Stapler (K071708, K073001) is a reference device with regard to the device assembly process.

**Device Description**

This is a bundled 510(k) that includes multiple individual component devices, as indicated in the table below.

| Trade Name | Catalog Number |
|---|---|
| Sonicision™ Reusable Generator | SCGAA |
| Sonicision™ Reusable Battery Pack | SCBA |
| Sonicision™ Curved Jaw Cordless Ultrasonic Dissector 5 mm – 13 cm | SCDA13 |
| Sonicision™ Curved Jaw Cordless Ultrasonic Dissector 5 mm – 26 cm | SCDA26 |
| Sonicision™ Curved Jaw Cordless Ultrasonic Dissector 5 mm – 39 cm | SCDA39 |
| Sonicision™ Curved Jaw Cordless Ultrasonic Dissector 5 mm – 48 cm | SCDA48 |
| Sonicision™ Reusable Battery Insertion Guide | SCBIGA |
| Sonicision™ Battery Charger | CBCA |

A functional Sonicision™ Curved Jaw Cordless Ultrasonic Dissection device is assembled by the user within the operating room. The functional device is assembled from the following three components: (1) a sterile, single-use dissector (SCDAxx), (2) a user cleaned and sterilized reusable generator (SCGAA), and (3), a user cleaned and disinfected reusable battery (SCBA). There are four different lengths of sterile single-use dissectors to allow surgeons a range of options to meet the needs of each specific surgical case.

The assembled functional device is a hand-held, battery-powered device used to dissect through tissues and to coagulate vessels up to and including 5 mm in diameter. 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 by pressing a button on the handpiece.

The 510(k) submission includes two accessories. The first is the Battery Insertion Guide (SCBIGA), a reusable, user-sterilized device that facilitates the assembly process.

The second accessory is a custom battery charger (CBCA). The charger is able to charge up to four SCBA batteries at a time. It provides the user with an indication of the charging progress. It also monitors battery health and the number of surgical uses the battery has gone through. It disables batteries that have reached end of life or that are out of specification.

**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 and including 5 mm in diameter.

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

**Technological Characteristics**

*Sonicision dissectors*

These are sterile single-use devices that include 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, positioning the jaws, and for opening and closing the clamping jaw
- A speaker to deliver audio signals

*Sonicision Reusable Generator*

This is a re-usable device that is cleaned and sterilized by the user facility. It has the following features

- Transducer that converts electrical energy into ultrasonic energy (resonant frequency of approximately 56.0 kHz)
- Indicator LED that notifies the user of the state of the assembled device
- Control software

*Sonicision Reusable Battery Pack*

This is a reusable device that is cleaned and disinfected by the user facility. It has the following features

- Li-ion chemistry
- 7.2 V
- Multiple internal safety protections

*Sonicision Reusable Battery Insertion Guide*

This is a reusable device that is cleaned and sterilized by the user facility. It is a molded plastic component that is designed to interface with the battery compartment of the single-use dissectors. It has the following features

- Keying features to assist with the assembly process
- Printed graphic showing the correct placement orientation

*Sonicision Battery Charger*

This is a custom battery charger that is compatible only with the SCBA battery. It has the following features

- Charging bays that are keyed to facilitate correct orientation of the SCBA batteries
- A user interface that indicates charging progress, if there is a problem with a battery, and if there is a problem with a charger bay.
- Monitors battery health and usage; disables batteries that have problems or are at end of life

**Comparison to the Predicate Device**

The table below compares the main device characteristics and performance of the Sonicision™ Curved Jaw Cordless Ultrasonic Dissection Device to the device characteristics and performance of the legally marketed Sonicision™ Cordless Ultrasonic Dissection Device.

| Characteristic | Sonicision Curved Jaw (Proposed Device) | Currently marketed Sonicision (Predicate Device) | Comment |
|---|---|---|---|
| Indications for Use | The Sonicision™ Curved Jaw 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 and including 5 mm in diameter.<br>The Sonicision 13 cm device is also indicated for use in otorhinolaryngologic (ENT) procedures. | 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.<br>The Sonicision 13 cm device is also indicated for use in otorhinolaryngologic (ENT) procedures. | The only difference is that the indicated vessel size is being changed from "up to 5 mm" to "up to **and including** 5mm."<br>This minor difference in vessel size range does not create a new intended use or raise new kinds of safety or effectiveness questions. The ability of the Sonicision Curved Jaw device to coagulate vessels that are 5 mm in diameter is supported by both bench testing and pre-clinical testing included within this submission. |
| Contraindications | The device is not indicated for incising bone.<br>The device is not intended for contraceptive tubal occlusion. | The device is not indicated for incising bone.<br>The device is not intended for contraceptive tubal occlusion. | Same |
| Operating Principle | Waveguide (also referred to as blade) vibrates at ultrasonic frequencies. The motion of the waveguide creates thermal and mechanical effects that disrupt cells and tissue. The user can also apply pressure with the passive jaw to achieve specific tissue effects (e.g., coagulating a vessel) | Waveguide (also referred to as blade) vibrates at ultrasonic frequencies. The motion of the waveguide creates thermal and mechanical effects that disrupt cells and tissue. The user can also apply pressure with the passive jaw to achieve specific tissue effects (e.g., coagulating a vessel) | Same |

| Characteristic | Sonicision Curved Jaw (Proposed Device) | Currently marketed Sonicision (Predicate Device) | Comment |
|---|---|---|---|
| Resonant frequency of operation | 56.0 kHz | 55.5 kHz | This is a very minor shift in resonant frequency associated with design changes in the proposed curved jaw device. |
| Cordless | Yes | Yes | Same |
| Assembly Required prior to use? | Yes | Yes | Some differences in the assembly process. |
| Power source type | Lithium-ion battery | Lithium-ion battery | Same |
| Instrument form factor | Shaft-based design, pistol grip | Shaft-based design, pistol grip | Same |
| Active blade length | 14.5 mm | 14.5 mm | Same |
| Jaw and active blade shape | Curved | Straight | The curve is an alternate design, which is a common feature of many surgical instruments. Testing showed equivalent performance to the predicate device. |
| Power Settings | Two power levels: minimum and maximum. | Two power levels: minimum and maximum. | Same |
| Audio Indicators - functional | Audio tones from the handset provide feedback that energy has been activated. The pitch of the tone correlates with minimum or maximum setting. | Audio tones from the handset provide feedback that energy has been activated. The pitch of the tone correlates with minimum or maximum setting. | Same |
| Audio indicators - errors | Audio tones with distinct patterns also indicate assembly errors, device malfunction, and low battery conditions. | Audio tones with distinct patterns also indicate assembly errors, device malfunction, and low battery conditions. | Same set of indications. |
| Visual Indicators | Visual indicators (LEDs) on top of device identify the state of the assembled device, battery, and generator. | Visual indicators (LEDs) on top of device identify the state of the assembled device, battery, and generator. | All of the original indicators are present, plus a new visual indicator related to generator status. |

The impact of these differences was evaluated through

(1) Comparative studies described below showing equivalent performance of the Sonicision Curved Jaw device and predicate Sonicision device.

(2) Comparison to a reference device, the i-Drive powered stapling device for aspects related to device assembly.

(3) Validation of cleaning, disinfection, and sterilization processes in accordance with FDA guidance.

(4) Extensive human factors evaluation with operating room nurses and surgical technicians, surgeons, and central processing.

**Standards Compliance**

The devices that make up the Sonicision™ Curved Jaw Ultrasonic Dissection Device and the accessories included in this 510(k) submission have been shown to meet the medical device standards listed below, as applicable.

- ISO 10993-1: 2009, Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process – Fourth Edition
- IEC 60601-1: 2005 + A1 2012, Medical electrical equipment – Part 1: General requirements for basic safety and essential performance – Edition 3.1
- IEC 60601-1-2: 2014, Medical electrical equipment – Part 1-2: General Requirements for Safety – Collateral Standard: Electromagnetic compatibility – Requirements and tests, 4th edition
- IEC 62133: 2012, Secondary cells and batteries containing alkaline or other non-acid electrolytes—Safety requirements for portable sealed secondary cells, and for batteries made from them, for use in portable applications
- IEC 62281: 2012, Safety of primary and secondary lithium cells and batteries during transport
- UN Manual of Tests and Criteria, 6th Edition, "Recommendations on the Transport of Dangerous Goods, Section 38.3 - Lithium Batteries"

The software development process was evaluated by a third party and found to meet the requirements of IEC 62304: 2006 (Medical device software — Software life cycle processes, 1st edition).

The human factors and usability engineering process was evaluated by a third party and found to meet the requirements of IEC 62366-1: 2015 (Medical devices. Application of usability engineering to medical devices).

**Performance**

The performance of the Sonicision™ Curved Jaw Cordless Ultrasonic Dissection Device was compared to the performance of the primary predicate device in several bench and animal tests, as described below. The results of this testing show comparable performance between the two device families.

- *Ex vivo* burst testing showed that blood vessels coagulated by the Sonicision Curved Jaw device had comparable burst strength to the same type of blood vessels coagulated by predicate Sonicision device.
- *Ex vivo* tissue testing showed that the maximum temperature of the Sonicision Curved Jaw active blade and shaft were comparable to the maximum temperatures of the predicate Sonicision active blade and shaft after multiple activations on mesentery.

- Acute *in vivo* testing showed that the Sonicision Curved Jaw device family and the predicate Sonicision device family achieved comparable rates of hemostasis and comparable lateral thermal spread.

Other tests demonstrated that the Sonicision Curved Jaw Cordless Ultrasonic Dissection Device family meets user needs and FDA expectations.

- Chronic *in vivo* testing showed that vessels (up and including 5 mm in diameter) coagulated by the Sonicision Curved Jaw device family maintain hemostasis for at least 21 days. Surgical sites showed an expected healing response.
- Human Factors and Usability validation demonstrated that the user interfaces and cleaning/sterilization instructions for the various devices included in this 510(k) are suitable for the intended user populations: OR staff (circulating nurses and surgical scrub nurses and technicians, surgeons from multiple surgical specialties, and central processing technicians.

**Conclusion**

The Sonicision™ Curved Jaw Cordless Ultrasonic Dissection Device family and accessories are substantially equivalent to the predicate Sonicision™ Cordless Ultrasonic Dissection Device family and accessories.