July 10, 2020

Covidien, LLC
Celso Duran
Principal Regulatory Affairs Specialist
5920 Longbow Dr.
Boulder, Colorado 80301

Re: K200427
Trade/Device Name: Sonicision Cordless Ultrasonic Dissector
Regulation Number: 21 CFR
Regulation Name: Instrument, Ultrasonic Surgical
Regulatory Class: Class II
Product Code: LFL
Dated: June 16, 2020
Received: June 17, 2020

Dear Celso Duran:

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,

Long Chen, Ph.D.
Assistant Director
DHT4A: Division of General Surgery Devices
OHT4: Office of Surgical
and Infection Control 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)*
K200427

Device Name
Sonicision™ Cordless Ultrasonic Dissector

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.

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

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510(k) Summary

Date summary prepared: February 19, 2020

510(k) Submitter/Holder
Covidien llc
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Boulder, CO 80301

Contact:
Celso Duran
Principal Regulatory Affairs Specialist
Telephone: (303) 530 - 6445
Email: celso.duran@medtronic.com

Name of Device

Trade Name:	Sonicision™ Cordless Ultrasonic Dissector
Catalog Number:	SCD13, SCD26, SCD391, SCD396, SCD48
Common Name:	Ultrasonic Dissector
Classification Name:	None Established (unclassified, product code LFL)

Predicate Device

Trade Name:	Sonicision™ Cordless Ultrasonic Dissector
Catalog Number:	SCD13, SCD26, SCD391, SCD396, SCD48
Common Name:	Ultrasonic Dissector
Classification Name:	None Established (unclassified, product code LFL)
510(k) Number:	K153371 (cleared March 28, 2016) - SCD13 K141371 (cleared August 7, 2014) - SCD13, SCD26, SCD48 K101797 (cleared February 24, 2011) - SCD391, SCD396
Manufacturer:	Covidien llc
Recalls:	This predicate has not been subject to a design-related recall.

The predicate for this submission is K153371, which expanded the indications for use of the SCD13 dissector. K141371 and K101797 are referenced in the table above as those submissions cumulatively provided clearance for all lengths of dissectors.

Reference Device

Trade Name:	Sonicision™ Curved Jaw Cordless Ultrasonic Dissector
Catalog Number:	SCDA13, SCDA26, SCDA39, SCDA48
Common Name:	Ultrasonic Dissector
Classification Name:	None Established (unclassified, product code LFL)
510(k) Number:	K180149 (cleared March 26, 2018)
Manufacturer:	Covidien llc

The reference device supports the use of well-established methods in this submission. The methods used in the reference device were found acceptable through K180149. Covidien is the manufacturer of both the reference and predicate device.

Device Description
The Sonicision™ Cordless Ultrasonic Dissector is a component of the Sonicision™ Cordless Ultrasonic Dissection Device, which 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 dissector is a sterile, single-use component to which the Sonicision reusable generators and battery packs attach. This component contains features essential to the control and performance of the assembled device; such as the clamping jaw, active blade, speaker, two-stage energy button, rotation wheel, and jaw lever.

Four configurations are available, differing principally by shaft length. The lengths are 13 cm, 26 cm, 39 cm, and 48 cm; corresponding with catalog numbers SCD13, SCD26, SCD391, SCD396, and SCD48, respectively. The only difference between SCD391 and SCD396 is the packaging configuration. There is no difference in the design of the device.

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
The Sonicision™ Cordless Ultrasonic Dissector 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.

Patient Contacting Materials
Patient contacting materials included in the manufacture of the Sonicision™ Ultrasonic Dissector include stainless steel, titanium, polycarbonate, thermoplastic elastomer, acrylonitrile butadiene styrene (ABS), and silicone.

Comparison of Technological Characteristics with the Predicate Device
The operating principle for both the subject and predicate devices is the same. The 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. At a high level, the subject and predicate devices are based on the following technological elements:
- Intended and indicated for the same types of surgeries
- Contraindications
- Resonant frequency, approx. 55.5 kHz
- Clamping jaws actuated using a lever
- Modes of operation: a minimum power mode that is used for vessel coagulation and a maximum power mode that is used for dissection

The following technological differences exist between the subject and predicate devices:
- Jaw force
- Force to fully close the jaw lever
- Tactile feedback during lever actuation

Performance Data

The performance of the Sonicision™ Cordless Ultrasonic Dissector was compared to the performance of the predicate device in several bench and animal tests, as described below. The following performance data were provided in support of the substantial equivalence determination:

- *Ex-vivo* burst testing showed that blood vessels coagulated by the Sonicision™ Cordless Ultrasonic Dissector had comparable burst strength to the same type of blood vessels coagulated by the predicate.
- *Ex-vivo* tissue testing showed that the maximum temperatures and cool down times of the Sonicision™ Cordless Ultrasonic Dissector's active blade and shaft were comparable to the maximum temperatures and cool down times of the predicate's active blade and shaft after multiple activations on mesentery.
- Acute *in-vivo* testing showed that the Sonicision™ Cordless Ultrasonic Dissector and the predicate achieved comparable rates of hemostasis and comparable lateral thermal spread.
- Chronic *in-vivo* testing showed that vessels (up to 5 mm in diameter) coagulated by the Sonicision™ Cordless Ultrasonic Dissector maintain hemostasis for at least 21 days.
- Human factors validation in a porcine model and a human cadaver model demonstrated that the Sonicision™ Cordless Ultrasonic Dissector meets user needs and FDA expectations.

Conclusions

The proposed Sonicision™ Cordless Ultrasonic Dissector is substantially equivalent to the predicate Sonicision™ Cordless Ultrasonic Dissector.