November 15, 2021

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

Re: K212301
Trade/Device Name: Sonicision 7 Curved Jaw Cordless Ultrasonic Dissection Device
Regulatory Class: Unclassified
Product Code: LFL
Dated: October 13, 2021
Received: October 14, 2021

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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K212301

Device Name
Sonicision™ 7 Curved Jaw Cordless Ultrasonic Dissector; Sonicision™ 7 Reusable Ultrasonic Generator; and Sonicision™ Reusable Battery

Indications for Use *(Describe)*

Sonicision™ 7 Curved Jaw Cordless Ultrasonic Dissector and Sonicision™ 7 Reusable Ultrasonic Generator

The Sonicision™ 7 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, gynecologic, urologic, and other open and endoscopic procedures. The device can be used to coagulate isolated vessels up to and including 7 mm in diameter, using the minimum mode. The device can be used to coagulate isolated vessels up to and including 5 mm in diameter, using the maximum mode.

The Sonicision™ 7 13 cm device is also indicated for use in otorhinolaryngologic (ENT) procedures.

Sonicision™ Reusable Battery

The Sonicision™ reusable battery pack is a non-sterile, rechargeable, lithium-ion battery that provides power to compatible surgical devices. For full device indications for use, reference the indications for use statements of the compatible devices.

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

Date summary prepared: November 11, 2021

510(k) Submitter/Holder
Covidien llc
5920 Longbow Drive
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™ 7 Curved Jaw Cordless Ultrasonic Dissection Device
Catalog Number:	SCD7A13, SCD7A26, SCD7A39, SCD7A48, SCG7AA, SCG7AB, SCBA
Common Name:	Ultrasonic Dissection Device
Classification Name:	None Established (unclassified, product code LFL)

Predicate Devices

Primary

Trade Name:	Sonicision™ Curved Jaw Cordless Ultrasonic Dissection Device
Catalog Number:	SCDA13, SCDA26, SCDA39, SCDA48, SCGAA, SCBA
Common Name:	Ultrasonic Dissection Device
Classification Name:	None Established (unclassified, product code LFL)
510(k) Number:	K180149 (cleared March 26, 2018)
Manufacturer:	Covidien llc
Recalls:	This predicate was the subject to a recall. The root cause of this recall was identified and corrected in the subject device.

Secondary

Trade Name:	Harmonic Ace +7
Catalog Number:	HARH23, HARH36, HARH45
Common Name:	Ultrasonic Dissection Device
Classification Name:	None Established (unclassified, product code LFL)
510(k) Number:	K132612 (cleared October 17, 2013)
Manufacturer:	Ethicon
Recalls:	This predicate has not been subject to a design-related recall.

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™ 7 Curved Jaw Cordless Ultrasonic Dissector 5 mm – 13 cm	SCD7A13
Sonicision™ 7 Curved Jaw Cordless Ultrasonic Dissector 5 mm – 26 cm	SCD7A26
Sonicision™ 7 Curved Jaw Cordless Ultrasonic Dissector 5 mm – 39 cm	SCD7A39
Sonicision™ 7 Curved Jaw Cordless Ultrasonic Dissector 5 mm – 48 cm	SCD7A48
Sonicision™ 7 Reusable Ultrasonic Generator	SCG7AA, SCG7AB
Sonicision™ Reusable Battery Pack	SCBA

A functional Sonicision™ 7 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, (2) a user cleaned and sterilized reusable generator, and (3) a user cleaned and disinfected reusable battery. 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 tissue and to coagulate vessels up to and including 7 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.

Indications for Use (SCD7AXX and SCG7AX)
The Sonicision™ 7 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, gynecologic, urologic, and other open and endoscopic procedures. The device can be used to coagulate isolated vessels up to and including 7 mm in diameter, using the minimum mode. The device can be used to coagulate isolated vessels up to and including 5 mm in diameter, using the maximum mode.

The Sonicision™ 7 13 cm device is also indicated for use in otorhinolaryngologic (ENT) procedures.

Contraindications (SCD7AXX and SCG7AX)
- The device is not indicated for incising bone.
- The device is not to be used for contraceptive tubal occlusion.

Indications for Use (SCBA)
The Sonicision™ reusable battery pack is a non-sterile, rechargeable, lithium-ion battery that provides power to compatible surgical devices. For full device indications for use, reference the indications for use statements of the compatible devices.

Contraindications (SCBA)
None known.

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

- Features that interface with the Sonicision generator and the Sonicision battery.

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

Patient Contacting Materials
Patient contacting materials included in the manufacture of the Sonicision™ 7 Curved Jaw Ultrasonic Dissection Device include stainless steel, titanium, Teflon (PTFE), polyamide, polycarbonate (PC), and silicone rubber.

Comparison of Technological Characteristics with the Predicate Devices
The operating principle for the proposed 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 proposed and predicate devices are based on the following technological elements:
- Intended use
- Contraindications
- 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 proposed and predicate devices:
- Dissectors
  - Jaw leg taper
- Generator
  - Software updates
  - LED updates
- Battery (SCBA)
  - Labeling

A more detailed comparison to the predicate is provided at the end of this summary (Table 1).

Performance Data
The performance of the Sonicision™ 7 Curved Jaw Cordless Ultrasonic Dissection Device was compared to the performance of the predicate devices in several bench and animal tests, as described below. The following performance data were provided in support of the substantial equivalence determination:
- Biocompatibility – Evidence was presented in the previously submitted primary predicate 510(k) [K180149]. The proposed device did not introduce any new materials when compared to the primary predicate.
- Software – The software of the proposed device was tested in accordance to "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices," issued May 11, 2005. The software development process used to develop the SCG7AX software met the requirements of the FDA-recognized standard IEC 62304: 2015.

- Electromagnetic compatibility - The assembled device was found to meet the applicable requirements of IEC 60601-1-2, 4th edition, Medical electrical equipment – Part 1-2: General Requirements for Safety – Collateral Standard: Electromagnetic compatibility – Requirements and tests.
- Electrical safety - The device was found to meet all applicable requirements of IEC 60601-1: 2005/ A1: 2012, Medical electrical equipment – Part 1: General requirements for basic safety and essential performance – Edition 3.1.
- *Ex-vivo* burst testing showed that blood vessels coagulated by the Sonicision™ 7 Curved Jaw Cordless Ultrasonic Dissection Device had comparable burst strength to the same type of blood vessels coagulated by the predicates.
- *Ex-vivo* tissue testing showed that the maximum temperatures and cool down times of the Sonicision™ 7 Curved Jaw Cordless Ultrasonic Dissection Device'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™ 7 Curved Jaw Cordless Ultrasonic Dissection Device and the predicates achieved comparable rates of hemostasis and comparable lateral thermal spread.
- Chronic *in-vivo* testing showed that vessels (up to and including 7 mm in diameter) coagulated by the Sonicision™ 7 Curved Jaw Cordless Ultrasonic Dissection Device maintain hemostasis for at least 21 days.
- Human factors activities demonstrate that the Sonicision™ 7 Curved Jaw Cordless Ultrasonic Dissection Device meets user needs and is able to be used for the intended users, intended use, and use environments.

Conclusions

The proposed Sonicision™ 7 Curved Jaw Cordless Ultrasonic Dissection Device is substantially equivalent to the predicate devices.

Table 1: Comparison of the Proposed and Predicate Devices

Characteristic	**Proposed Device** **Sonicision™ 7 Dissection Device (SCD7AXX, SCG7AX, SCBA)**	**Primary Predicate Device** **Sonicision™ Dissection Device (K180149)**	**Secondary Predicate Device** **Harmonic Ace +7 (K132612)**	**Comment**
Class	None Established	None Established	None Established	Identical
Product Code	LFL	LFL	LFL	Identical
Intended Use	Vessel coagulation using ultrasonic energy	Vessel coagulation using ultrasonic energy	Vessel coagulation using ultrasonic energy	Identical
Maximum Vessel Diameter Coagulation	7 mm	5 mm	7 mm	The performance testing demonstrated the proposed device is able to coagulate vessels up to and including 7 mm

Characteristic	**Proposed Device** Sonicision™ 7 Dissection Device (SCD7AXX, SCG7AX, SCBA)	**Primary Predicate Device** Sonicision™ Dissection Device (K180149)	**Secondary Predicate Device** Harmonic Ace +7 (K132612)	Comment
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)	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)	Identical
Cordless	Yes	Yes	No	Identical to primary predicate
Assembly required prior to use?	Yes	Yes	Yes	Identical
Instrument form factor	Shaft-based design	Shaft-based design	Shaft-based design	Identical
Power source type	Lithium-ion battery	Lithium-ion battery	Generator	Identical to primary predicate
Power settings	The Sonicision device has two power levels: minimum and maximum.	The Sonicision device has two power levels: minimum and maximum.	The Harmonic Ace +7 has three power levels: minimum, maximum, and advanced hemostasis.	Identical to primary predicate
Power output algorithm	Power varied according to load in order to achieve constant displacement.	Power varied according to load in order to achieve constant displacement.	Power varied according to load in order to achieve constant displacement.	Identical
Software	Software modified to allow for 7 mm coagulation using minimum mode.	Software allows for 5 mm coagulation.	Software allows for 7 mm coagulation.	The performance testing demonstrated the proposed device is able to coagulate vessels up to and including 7 mm.
LED	Change in LED driver and component manufacturer	Current LED driver and component manufacturer	N/A	Part is equivalent to primary predicate.
Jaw leg taper	Taper added to jaw leg	No jaw leg taper	N/A	The performance testing demonstrated the proposed device is able to coagulate vessels up to and including 7 mm.