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

August 7, 2014

Covidien
Mr. David M. Horton
Manager, Regulatory Affairs
5920 Longbow Drive
Boulder, Colorado 80301

Re: K141371
Trade/Device Name: Sonicision™ Cordless Ultrasonic Dissection Device
Regulatory Class: Unclassified
Product Code: LFL
Dated: July 17, 2014
Received: July 18, 2014

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 contact the Division of Industry and Consumer Education 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" (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 Industry and Consumer Education 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,

David Krause -S

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)*
K141371

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.

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)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

Joshua C. Nipper -A

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

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510(k) Summary

Date summary prepared: 5/23/2014

510(k) Submitter/Holder
Covidien
5920 Longbow Drive
Boulder, CO 80301

Contact
David Horton
Manager, Regulatory Affairs
Telephone: 303-530-6391
Fax: 303-530-6313
Email: david.m.horton@covidien.com

Name of Device

Trade Name:	Sonicision™ Cordless Ultrasonic Dissector
Catalog Numbers:	SCD13, SCD26, SCD48
Common Name:	Instrument, Ultrasonic Surgical
Classification Name:	Unclassified (product code LFL)

Predicate Device

Trade Name:	Sonicision™ Cordless Ultrasonic Dissector
Common Name:	Instrument, Ultrasonic Surgical
Catalog Number:	SCD391, SCD396
510(k) Number:	K101797 (cleared 2/24/2011)
Manufacturer:	Covidien

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 (cleared through K101797), and 48 cm; corresponding with catalog numbers SCD13, SCD26, SCD391/6, and SCD48, respectively.

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

Qualitative and quantitative data were obtained and used to compare the three proposed Sonicision dissectors to the predicate dissector. All aspects were found to be identical, with the exception of the shaft length and measurement marks.

The shaft-length differences were found to not affect safety or performance through design verification and validation testing; specifically, through continued conformance to applicable technical design specifications and performance requirements, industry safety and performance standards, and other nonclinical testing.

Bench testing to evaluate electrical/mechanical characteristics:

- Basic safety and essential performance in accordance with AAMI ES60601-1:2005
- Electromagnetic compatibility in accordance with IEC 60601-1-2:2007
- Active blade displacement
- Active blade frequency
- Shaft deflection
- Jaw clamping force
- Packaging performance
- System compatibility

Bench testing to evaluate performance characteristics using excised porcine tissue:

- Burst pressures/hemostasis of isolated vessel up to 5mm in diameter
- Coagulation/Dissection speed
- Temperature of the active blade and shaft

Preclinical testing to evaluate (device and human factors) performance on tissue bundles and isolated vessels up to 5mm in diameter using porcine:

- Acute hemostasis
- Thermal spread
- Chronic hemostasis
- Human factors and usability

This premarket submission did not rely on the assessment of clinical performance data to demonstrate substantial equivalence.

Through the comparison of technological and performance characteristics, the proposed Sonicision™ dissectors (SCD13, SCD26, SCD48) were found to be substantially equivalent to the predicate device.