Covidien
Candice Bautista-Biddle
Associate Regulatory Affairs Specialist
5920 Longbow Drive
Boulder, Colorado 80301

Re: K180915
Trade/Device Name: Sonicision Reusable Sterilization Tray
Regulation Number: 21 CFR 880.6850
Regulation Name: Sterilization Wrap
Regulatory Class: Class II
Product Code: KCT
Dated: June 26, 2018
Received: June 27, 2018

Dear Candice Bautista-Biddle:

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 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,

Clarence W. Murray Iii III -S

For Tina Kiang, Ph.D.
Acting Director
Division of Anesthesiology,
General Hospital, Respiratory,
Infection Control, and Dental 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K180915

Device Name
Sonicision™ Reusable Sterilization Tray

Indications for Use *(Describe)*
The Sonicision™ reusable sterilization tray is intended to provide storage for the Sonicision™ reusable generator and Sonicision™ reusable battery insertion guides during sterilization, storage, and transportation within the hospital environment. The Sonicision™ reusable sterilization tray is only intended to maintain sterility of the enclosed components during autoclave sterilization when used in conjunction with an FDA-cleared sterilization wrap or rigid container (validated with Aesculap™* rigid container model JN741/JK789). The sterilization tray has only been evaluated for a non-stacked configuration.

The validated sterilization cycle parameters are as follows:

Steam Sterilization Cycles

Cycle Type	Exposure Temperature	Exposure Time (minutes)	Minimum Dry Time[1] (minutes)	Compatible Sterile Barriers
Pre-vacuum	132 °C (270 °F)	4	40	Wrap(s) and rigid container[2]
Pre-vacuum	135 °C (275 °F)	3	40	Wrap(s) and rigid container[2]
Gravity	132 °C (270 °F)	15	40	Wrap(s)
Gravity	135 °C (275 °F)	10	30	Wrap(s)

[1] Due to variations in autoclave sterilization equipment, actual dry times may vary from the minimum dry times validated for this product.
[2] Validated with Aesculap™* rigid container model JN741/JK789.

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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COVIDIEN

510(k) Summary: K180915

Date summary prepared: 7/16/2018

510(k) Submitter/Holder

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Contact

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Name of Device

Trade Name:	Sonicision™ Reusable Sterilization Tray
Common Name:	Sterilization Tray
Catalog Numbers:	SCSTA
Classification Name:	Sterilization Wrap Containers, Trays, Cassettes and Other Accessories (21 CFR 880.6850, Class II, KCT)

Predicate Device

Trade Name:	Signia™ Sterilization Tray
Catalog Numbers:	SIGTRAY
Common Name:	Sterilization Tray
Classification Name:	Sterilization Wrap Containers, Trays, Cassettes and Other Accessories (21 CFR 880.6850, Class II, KCT)
510(k) Number:	K161347
Manufacturer:	Covidien

Device Description

The Sonicision Sterilization Tray is a reusable, optional accessory to the Sonicision System (cleared through K180149). This device is specially made to enclose up to one Sonicision Reusable Generator and up to two Sonicision Reusable Battery Insertion Guides in order to provide storage during sterilization, storage, and transportation within the hospital environment. The tray does not provide a sterile barrier on its own; it can only maintain sterility using an FDA-cleared sterilization wrap or rigid container.

Indications for Use

The Sonicision™ reusable sterilization tray is intended to provide storage for the Sonicision™ reusable generator and Sonicision™ reusable battery insertion guides during sterilization, storage, and transportation within the hospital environment. The Sonicision™ reusable sterilization tray is only intended to maintain sterility of the enclosed components during autoclave sterilization when used in conjunction with an FDA-cleared sterilization wrap or rigid container (validated with Aesculap™* Rigid Container model JN741/JK789). The sterilization tray has only been evaluated for a non-stacked configuration.

The validated sterilization cycle parameters are as follows:

Steam Sterilization Cycles

Cycle Type	Exposure Temperature	Exposure Time (minutes)	Minimum Dry Time[1] (minutes)	Compatible Sterile Barriers
Pre-vacuum	132 °C (270 °F)	4	40	Wrap(s) and rigid container[2]
Pre-vacuum	135 °C (275 °F)	3	40	Wrap(s) and rigid container[2]
Gravity	132 °C (270 °F)	15	40	Wrap(s)
Gravity	135 °C (275 °F)	10	30	Wrap(s)

[1]Due to variations in autoclave sterilization equipment, actual dry times may vary from the minimum dry times validated for this product.

[2]Validated with Aesculap Rigid Container model JN741/JK789

Comparison of Technological Characteristics with the Predicate Device

Both the proposed and predicate devices have the same intended use of providing storage for components of their respective systems during sterilization, storage, and transportation within the hospital environment. Additionally, both devices have the same basic design of tray and lid with perforations to allow for steam sterilization of the enclosed devices.

	Subject Device Sonicision Reusable Sterilization Tray	Predicate Device K161347 Signia sterilization tray
Enclosed devices for sterilization	The tray can contain at a maximum: One (1) Sonicision Reusable Generator, Two (2) Sonicision Reusable Battery Insertion Guides.	The tray can contain at a maximum: One (1) Signia Adapter, One (1) Signia Reusable Insertion Guide and One (1) Signia Manual Retraction Tool.
Dimensions	Approx. 8.5 x 11.0 x 3.0 (H) inches	Approx. 10.0 x 21.4 x 3.0 (H) inches
Sterilization methods	Steam (Pre-vacuum and Gravity)	Steam (Pre-vacuum)
Steam sterilization parameters	**132 °C Pre-vacuum Steam Cycle** Exposure temperature: 270 °F (132 °C) Exposure time: 4 minutes Minimum dry time: 40 minutes **135 °C Pre-vacuum Steam Cycle** Exposure temperature: 275 °F (135 °C) Exposure time: 3 minutes Minimum dry time: 40 minutes	**132 °C Pre-vacuum (Hi Vac) Steam Cycle** Exposure temperature: 270 °F (132 °C) Exposure time: 4 minutes Vacuum dry time: 20-40 minutes **134 °C Pre-vacuum (Hi Vac) Steam Cycle** Exposure temperature: 273 °F (134 °C) Exposure time: 3 minutes Vacuum dry time: 20-40 minutes
	132 °C Gravity Steam Cycle Exposure temperature: 270 °F (132 °C) Exposure time: 15 minutes Minimum dry time: 40 minutes **135 °C Gravity Steam Cycle** Exposure temperature: 275 °F (135 °C) Exposure time: 10 minutes Minimum dry time: 30 minutes	Not applicable

	Subject Device Sonicision Reusable Sterilization Tray	Predicate Device K161347 Signia sterilization tray
Base and Lid Materials	Base: Polyphenylsulfone Lid: Stainless Steel	Base and Lid: Stainless Steel
Stacking	Do not stack loaded/wrapped sterilization trays in chamber.	Do not stack cases and trays in the sterilization chamber.
Max. Load Capacity	< 1800 grams (3.97 pounds, including tray)	10 pounds

Performance Data
The following performance data were provided in support of the substantial equivalence determination.

Cleaning and Sterilization Testing
Cleaning and sterilization testing was performed in accordance with ANSI/AAMI/ISO 17665-1, AAMI TIR30:2011, AAMI TIR12:2010, and FDA Guidance, "Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling Guidance for Industry and Food and Drug Administration Staff" published March 17, 2015.

Mechanical/Reliability Testing
Mechanical and reliability testing was carried out to verify that the proposed device performs as expected at initial use and after repeated cleaning and sterilization cycles.

Human Factors Validation Testing
Human factors testing was performed in accordance with IEC 62366-1:2015 along with FDA Guidance, "Applying Human Factors and Usability Engineering to Medical Devices" published February 3, 2016 to verify that intended users are able to safely and correctly use the device.

Conclusion
The performance data support that the Sonicision Reusable Sterilization Tray is as safe, as effective, and performs as well or better than the legally marketed predicate device.