COVIDIEN

510(k) Summary

Date summary prepared: August 23, 2013

510(k) Submitter/Holder
Covidien
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AUG 2 8 2013

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Name of (Subject) Device
Trade Name: Sonicision™ Sterilization Tray
Common Name: Sterilization Tray
Classification Name: Sterilization wrap containers, trays, cassettes & other accessories
Device Class: II
Classification Regulation: 21 CFR 880.6850
Product Code: KCT

Predicate Devices
The sterilization tray described in this submission was compared and found to be substantially equivalent to the following sterilization trays in commercial distribution:

Trade Name: Sonicision™ Sterilization Tray
510(k) Number: K112536, cleared 4/19/2012
Manufacturer: Covidien

Trade Name: V-PRO® Sterilization Tray
510(k) Number: K070769, cleared 10/5/2007
Manufacturer: STERIS Corporation

Trade Name: FinESS™ Endoscope Sterilization Tray
510(k) Number: K103213, cleared 2/2/2011
Manufacturer: Entellus Medical, Inc.

Device Description
The Sonicision™ Sterilization Tray is intended to hold and protect Sonicision generators and battery packs during sterilization and storage, as indicated. It is comprised of a polysulfone base containing silicone inserts and a removable/latching polysulfone lid. The tray is reusable and provided to the customer in a non-sterile condition. Perforations on the lid and base permit

exposure of the sterilant. Handles on the sides of the base facilitate transfer of the sterilized components, and the contoured inserts secure the contents within the tray.

The Sonicision™ Sterilization Tray does not contain gaskets, filters, or valves to act as a barrier to microorganisms during storage, handling, and transport. The tray containing its intended content (load) must be wrapped with an FDA-cleared STERRAD or STERIS V-PRO-compatible polypropylene sterilization wrap or pouched with an FDA-cleared STERRAD or STERIS V-PRO-compatible Tyvek® pouch (note: the wrap and pouch are not supplied by Covidien) and sterilized as instructed by the labeling.

Intended Use
The Sonicision Sterilization Tray is intended to be used to encase and protect reusable battery packs and generators of the Sonicision system during sterilization and storage. The tray containing up to one generator and one battery pack (maximum load) can be used with the following models and pre-set (non-adjustable) cycles.

Model	Cycle
STERRAD® 100S	Standard
STERRAD® NX®	Standard
STERRAD® 100NX®	Standard
STERIS Amsco® V-PRO® 1	Lumen
STERIS Amsco® V-PRO® 1 Plus	Lumen
STERIS Amsco® V-PRO® maX	Lumen

Maintenance of sterility of the content within the tray is based on demonstrated performance of the sterilization wrap or pouch used to encase the tray.

Technological and Performance Characteristics
The proposed Sonicision tray was found to be similar to the predicate trays in several ways. Three fundamental similarities are identified and discussed below:

(1) Basic design – All trays are reusable accessories designed as two-part (lid/base) systems with latches, handles, perforations, and contoured inserts intended to contain items for sterilization, storage, transportation, aseptic presentation of contents, and return of contaminated items to the decontamination area. Notably other design aspects, such as the general shape, size, weight, and materials, though not identical, are similar.

(2) Role in the sterile barrier system – Neither the proposed tray nor the predicate trays contain gaskets, valves, or filters – they must all be enclosed with a qualified FDA-cleared sterilization wrap or pouch to maintain sterility.

(3) Fundamental technology – All trays rely on surface perforations (holes or other openings) to allow the sterilant to penetrate and render its content sterile.

The primary differences between the predicate and proposed trays are variances in shape, size, weight, intended content, and surface perforations. Although a small difference in percent of surface perforations is noted, performance data demonstrate that the difference does not adversely affect safety and effectiveness. A comparison of the proposed device to the predicate devices is provided on the next page.

510(k) Summary - Comparison Table

	Proposed: Sonicision™ Sterilization Tray	**Predicate: Sonicision™ Sterilization Tray, K112536**	**Predicate: V-PRO® Sterilization Tray, K070769**	**Predicate: FinESS™ Endoscope Sterilization Tray, K103213**
Intended Use	To encase and protect reusable batteries and generators of the Sonicision system during sterilization and storage. Compatible sterilization systems are indicated as follows: -STERRAD® 100S -STERRAD® NX® -STERRAD® 100NX® -STERIS Amsco® V-PRO® 1 -STERIS Amsco® V-PRO® 1 Plus -STERIS Amsco® V-PRO® maX	To encase and protect reusable batteries and generators of the Sonicision system during sterilization and storage. Compatible sterilization systems are indicated as follows: -STERRAD® 100S	To contain, transport, and store reusable medical devices for sterilization. Compatible sterilization systems are indicated as follows: -STERIS Amsco® V-PRO® 1 -STERIS Amsco® V-PRO® 1 Plus -STERIS Amsco® V-PRO® maX	To encase and protect the FinESS Endoscope for sterilization. Compatible sterilization systems are indicated as follows: -STERRAD® NX® -STERRAD® 100NX®
Design Characteristics				
Composition	Base and lid	Identical to proposed tray	Base and lid	Base and lid
Intended Content (maximum load)	One Sonicision generator and one battery pack	Identical to proposed tray	Reusable medical instrument(s), as indicated by size and weight	One FinESS™ Endoscope
Inserts	Yes. Designed to secure intended content	Identical to proposed tray	Yes. Various. Designed to secure intended content	Yes. Designed to secure intended content
Handles	Yes	Identical to proposed tray	Yes	No
Latches	Yes	Identical to proposed tray	Yes	Yes
Reusable	Yes	Identical to proposed tray	Yes	Yes
Materials of Construction				
Lid/Base	Polysulfone	Identical to proposed tray	Noryl resin	Polyetherimide
Inserts	Silicone	Identical to proposed tray	Polypropylene	Silicone
Latch	Polysulfone	Identical to proposed tray	304 Stainless Steel	Polyetherimide

	Proposed: Sonicision™ Sterilization Tray	**Predicate: Sonicision™ Sterilization Tray, K112536**	**Predicate: V-PRO® Sterilization Tray, K070769**	**Predicate: FinESS™ Endoscope Sterilization Tray, K103213**
Dimensions				
Assembled (L×W)	5.9 in. × 8.1 in.	Identical to proposed tray	10 in. × 14 in.	7.6 in × 4.1 in.
Weight				
Containing intended content (Max Load)	1.58 lbs (1 battery and 1 generator)	Identical to proposed tray	5.16 lbs (various reusable medical devices)	11.61 oz (one endoscope)
Fundamental Technology				
Percent of surface perforations	9.7%	Identical to proposed tray	5%	1%

Non-Clinical Performance Studies
Objective test evidence supporting sterilization efficacy, hydrogen peroxide residuals, material compatibility, biocompatibility, and mechanical performance were provided in the submission. A brief description of all tests used to support the conclusion of substantial equivalence with the predicate devices is provided as follows:

Sterilization efficacy: Sonicision Sterilization Trays containing the intended maximum load (one reusable battery pack and one reusable generator) were inoculated with geobacillus stearothermophilus. The biological indictor containing the indicator organism was placed in areas of the battery pack, generator, and sterilization tray determined to be the most difficult (worst-case) for the sterilant to penetrate. Following inoculation, the sterilization trays were either wrapped with an FDA-cleared STERRAD or STERIS V-PRO-compatible polypropylene wrap or enclosed in an FDA-cleared STERRAD or STERIS V-PRO-compatible Tyvek® Pouch. The loaded, inoculated, and wrapped or pouched trays were then exposed to the Standard cycles of the STERRAD® NX® and 100NX® systems, or the Lumen cycle of the STERIS Amsco® V-PRO® system. The results show that the indicated STERRAD and STERIS "half cycles" provided a six-log reduction of the indicator organism.

Sterilant Residuals: Residuals testing by ultraviolet/visible (UV/VIS) spectroscopy compared the measured results of the Sonicision tray's load with those obtained for a reference predicate tray's load. The study consisted of three runs of loaded (one battery pack and one generator), wrapped, or pouched Sonicision trays placed in STERRAD or STERIS systems. Testing of the reference predicate tray consisted of at least one run of loaded placed in STERRAD or STERIS systems. The products were exposed to Standard cycles of each STERRAD NX® and 100NX®, and Lumen cycle of the STERIS Amsco® V-PRO® model. The results show that the Sonicision Sterilization Tray permits adequate dissipation of hydrogen peroxide on the load when compared to the predicate devices used in the study.

Use Life (Material Compatibility): Life testing required all key functional/performance specifications of the tray to be evaluated after being subjected to complete reprocessing cycles using a worst-case methodology. The worst-case sterilization systems and cycles chosen for testing were the STERRAD 100NX with Standard cycle, and the STERIS V-Pro with Lumen cycle. The protocol required the tray to be assembled and disassembled, cleaned, disinfected, dried and sterilized repeatedly (340 cycles) using the methods and tools identified in the labeling. The results show the tray meets its performance specifications when reprocessed repeatedly in accordance with the labeling.

Biocompatibility: Biocompatibility testing was performed using a worst-case methodology by exposing the Sonicision Sterilization Tray to two full cycles (as indicated) of the STERRAD and STERIS systems. Test samples were prepared in accordance with ISO 10993-12:2007, Part 12: Sample Preparation and Reference Materials. All biocompatibility assays were performed on neat extracts. A quantitative assessment was made in accordance with applicable requirements of ISO 10993-5:2009, Part 5: Tests for *In Vitro* Cytotoxicity. The results show that the Sonicision Sterilization Tray passes all applicable biocompatibility requirements and is, therefore, considered non-cytotoxic following exposure to the intended sterilization systems.

Mechanical/Bench: The Sonicision Sterilization Tray was evaluated in accordance with applicable clauses/criteria specified in AAMI ST77:2006. The results show that all requirements were met.

Conformance to Standards and Guidance

The Sonicision Sterilization Tray conforms to applicable clauses of FDA-recognized consensus standard, AAMI ST77:2006, and draft FDA Guidance Document, "Premarket Notification [510(k)] Submissions for Medical Sterilization Packaging Systems in Health Care Facilities; Draft Guidance for Industry and FDA" (March 7, 2002). Notably, conformance to this standard and guidance document rely on adherence to the requirements and procedures of the following national and international standards: ISO 10993-1:2003 (Biocompatibility), AAMI ST81:2004 (Labeling), ISO 14937:2009 (Sterilization).

Clinical Performance Studies

This premarket notification report does not rely on the assessment of clinical performance data to demonstrate substantial equivalence.

Conclusion

The Sonicision™ Sterilization Tray subject to this submission is substantially equivalent to the Sonicision™ Sterilization Tray (K112536), V-PRO® Sterilization Tray (K070769), and the FinESS™ Endoscope Sterilization Tray (K103213). None of the differences between the Sonicision tray and the predicate trays change the intended use or raise new questions of safety or effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

August 28, 2013

Covidien
Mr. David M. Horton
Products Manager, Regulatory Affairs
5920 Longbow Drive
BOULDER CO 80301

Re: K131170
Trade/Device Name: Sonicision™ Sterilization Tray
Regulation Number: 21 CFR 880.6850
Regulation Name: Sterilization Tray
Regulatory Class: II
Product Code: KCT
Dated: August 2, 2013
Received: August 6, 2013

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 Small Manufacturers, International and Consumer Assistance 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 Small Manufacturers, International and Consumer Assistance 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,

Mary S. Runner -S

Kwame Ulmer M.S.
Acting Division Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and
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Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number (if known): K131170

Device Name: Sonicision™ Sterilization Tray

Indications for Use:
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Model	Cycle
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STERIS Amsco® V-PRO® 1 Plus	Lumen
STERIS Amsco® V-PRO® maX	Lumen

Maintenance of sterility of the content within the tray is based on demonstrated performance of the sterilization wrap or pouch used to encase the tray.

Prescription Use _____ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use ✓ (21 CFR 801 Subpart C)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Sreekanth Gutala -S
2013.08.28 13:57:43 -04'00'

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Respiratory, Infection Control and
Dental Devices
510(k) Number: ___k131170_____