K090068

510(k) Summary of Safety and Effectiveness

SteriTite Universal Container System with MediTray Products for Steris Amsco V-PRO 1 low temperature Sterilization System

Date Prepared: February 22, 2010

FEB 24 2010

Company Name: Case Medical, Inc.
65 Railroad Avenue
Ridgefield, NJ 07657

Contact: Tania Lupu
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Trade Name: *SteriTite*® universal container system
Common Name: Sterilization container with disposable filter.
Establishment registration number: 2248608
Classification name: Sterilization Wrap
Class of Device: Class II device,
Product Code: 80FRG
Review Panel: General Hospital
Legally Marketed Predicate: SteriTite universal container system previously cleared for STERRAD 200 and STERRAD NX, 510k # K080558

Indications for Use:

The SteriTite universal container system with MediTray products is a reusable sterilization container system used to enclose other medical devices, which are to be sterilized, transported and stored by a health care provider. The SteriTite container system is intended for use in Steris Amsco V-PRO 1 low temperature Sterilization System Lumen Cycle.

SteriTite Sealed Container system is recommended for surface and stainless steel lumens (process up to 20 stainless steel lumened instruments of 3mm diameter or larger and a length up to 400 mm or shorter).

Description of the Device:

The SteriTite universal container system consists of a family of rigid reusable containers and inserts that provide an effective sterilization packaging method for operating room instruments. The *SteriTite*® container is made out of anodized aluminum with passivated stainless steel hardware and silicone gaskets. Stainless steel latching mechanism with handles on both ends secures the lid to the base and provides a method to incorporate tamper proof disposable locks. Each filter retention plate secures a disposable filter for bacterial barrier filtration. Various instrument trays as well as stacked baskets and inserts provide instrument protection and secure devices for sterilization within the container. The

lids and bases as well as retention plates of the same model and size are compatible and interchangeable throughout its useful life. Vent holes are offset to prevent strike through. All components may be easily disassembled for cleaning.

Performance Data

Case Medical, Inc. follows the "overkill method" of sterility assurance to show an elimination of a biological challenge. Microbial challenge testing included placement of biological indicators and inoculated products in the most difficult-to-sterilize areas of the container in opposing corners, under the lid, inside of lumens, within insert boxes, and under occlusion within the slot of an instrument bracket securing a surgical instrument. The lumens tested were stainless steel lumens of 3 mm diameter x 400mm length.

All containers were tested with inner baskets or trays representative of the MediTray line of products.

Furthermore, sample containers were validated in worst-case scenarios.

Substantial Equivalence:

Case Medical's SteriTite container system is substantially equivalent to the company's previously cleared device for STERRAD 200. All containers are of equivalent sizes, have gasketed lids that latch, and offer tamper evident features.

References:

ANSI/AAMI ST 77:2006 – Containment Devices for Reusable Medical Devices Sterilization
ANSI/AAMI ST 79:2006 – Comprehensive Guide to Steam Sterilization and Sterility Assurance in Health Care Facilities

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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Re: K090068
Trade/Device Name: SteriTite Universal Container System and MediTray Products
Regulation Number: 21 CFR 880.6850
Regulation Name: Sterilization Wrap
Regulatory Class: II
Product Code: FRG
Dated: February 11, 2010
Received: February 16, 2010

Dear Ms. Lupu:

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 go to http://www.fda.gov/AboutFDA/CentersOffices/ CDRH/CDRHOffices/ ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. 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,

Susan Runner

for Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): _K090068_____

Device Name: SteriTite Universal Container System and MediTray products

Indications for Use:

The SteriTite universal container system with MediTray products is a reusable sterilization container system used to enclose other medical devices, which are to be sterilized, transported and stored by a health care provider. The SteriTite container system is intended for use in Steris Amsco V-PRO 1 low temperature Sterilization System Lumen Cycle.

SteriTite Sealed Container system is recommended for surface and stainless steel lumens (process up to 20 stainless steel lumened instruments of 3mm diameter or larger and a length up to 400 mm or shorter).

The table below identifies the SteriTite Sealed Containers with disposable filter , which may be sterilized in Steris Amsco V-PRO 1 low temperature Sterilization System:

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

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K090068

Part Number	Description	Steris Amsco V-PRO 1 w/ polypropylene disposable filter	Maximum load (lbs) inclusive of sealed container weight
SC03MG	3" high Endo mini-size w/ perforated base	X	5.63
SC03QG	3" high Endo mid-size w/ perforated base	X	8.85
SC04FG	4" high Full-size w/ perforated base	X	19.97
SC04HG	4" high Half-size w/ perforated base	X	9.90
SC04QG	4" high Mid-size w/ perforated base	X	15.70
SC06FG	6" high Full-size w/ perforated base	X	19.97
SC06HG	6" high Half-size w/ perforated base	X	13.16
SC06QG	6" high Mid-size w/ perforated base	X	19.97
SC08FG	8" high Full-size w/ perforated base	X	19.97
SC08HG	8" high Half-size w/ perforated base	X	15.92
SC08QG	8" high Mid-size w/ perforated base	X	19.97
SC05WG	5" high Extra Wide w/ perforated base	X	19.97

Note: All containers for Steris Amsco V-PRO 1 low temperature Sterilization System are perforated bottom containers, which must be used with single-use non-woven Polypro filter.

MediTray Products Compatibility Table

MEDITRAY PRODUCT	Steris Amsco V-PRO 1
Baskets	X
Trays	X
Insert Boxes	X
Metal Brackets	X
Metal Partitions	X
Posts	X
Silicone Brackets	X
Racks	X
Stringers	X

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

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Division of Anesthesiology, General Hospital Infection Control, Dental Devices

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