K080558

DEC 0 5 2008

5. 510(k) Summary of Safety and Effectiveness

SteriTite Universal Container System with MediTray Products for STERRAD 200, STERRAD NX, Ozone 125L Sterilization, and Prevacuum Steam Flash Sterilization

Date Prepared: October, 14 2008

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

Contact: Tania Lupu
Phone: 201-313-1999 ext.229
Fax: 201-313-9090

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

Indications for Use:

The SteriTite universal container system with MediTray products is a reusable sterilization container system intended to be used to enclose other medical devices (blades and lumens), which are to be sterilized, transported and stored by a health care provider.

The SteriTite container system is intended for use in STERRAD 200, STERRAD NX and Ozone 125L sterilizers, as well as the sealed containers are intended for pre-vacuum steam flash sterilization (270°F for 4 minutes).

The SteriTite perforated bottom container with disposable polypropylene filters (Polypro) must be used for STERRAD Sterilization. The paper filter is recommended for pre-vacuum steam flash sterilization. For ozone sterilization, either disposable paper or polypropylene filters can be used.

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 has both solid and perforated base containers. The container is made out of anodized aluminum with passivated stainless steel hardware and

silicone gaskets. A stainless steel latching mechanism with handles on both ends secures the lid to the base and provide 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 are as follows:

Sterilization Method	Max Diameter Lumen	Max Length Lumen	Material
STERRAD 200 Sterilization	3 mm	400 mm	Stainless Steel Blades, Lumens and Mixed Loads
STERRAD NX Standard cycle	2 mm	400 mm	Stainless Steel Blades, Lumens and Mixed Loads
STERRAD NX Advance cycle	1 mm	500 mm	Stainless Steel Blades, Lumens and Mixed Loads
	1 mm	850 mm	Porous Lumens (Flexible endoscope)
Pre-Vacuum Flash with paper filter Sterilization	2 mm	400 mm	Stainless Steel Blades, Lumens and Mixed Loads
	3 mm	400 mm	Porous Lumens
Ozone 125L Sterilization	3 mm	470 mm	Stainless Steel Blades, Lumens and Mixed Loads

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. In STERRAD NX and STERRAD 200 Sterilization the maximum load was 22lbs. (STU 10 kg) including the container. In Pre-Vacuum Steam Sterilization and Ozone 125L Sterilization, the maximum load was 35lbs. (15.8 kg.) total weight. The test samples represented a worst-case scenario in the SteriTite line of product based on number of holes (vents) per container volume. Internal stacking of trays and utilization of components was also validated under fractional and half

cycle conditions. Validation testing utilizing replicate cycles was conducted in independent laboratories in accordance with available AAMI standards.

Substantial Equivalence:

Case Medical's SteriTite container system is substantially equivalent to the company's previously device as well as Aesculap's Sterilcontainer in STERRAD 100s and Ozone 125L, as well as Aesculap's Sterilcontainer and One Tray for prevacuum steam sterilization. The SteriTite container system is the same container previously cleared. However, the STERRAD compatible Aesculap Sterilcontainer is made out of non-anodized aluminum and is thus a different Aesculap Sterilcontainer than that used for steam sterilization. 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
9200 Corporate Boulevard
Rockville MD 20850

Ms. Tania Lupu
Quality Assurance – Quality Control Director
Case Medical, Incorporated
65 Railroad Avenue
Ridgefield, New Jersey 07657-0402

DEC 0 5 2008

Re: K080558
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: November 13, 2008
Received: November 28, 2008

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.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such 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); 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.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. 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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Chiu S. Lin, Ph. D
Division 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): _____

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 STERRAD 200, STERRAD NX and Ozone 125L sterilizers, as well as the sealed containers are intended for pre-vacuum steam flash sterilization (270°F for 4 minutes). The container may be used for sterilization of medical devices including full instrument sets and mixed loads.

SteriTite Sealed Container system is recommended for surface and lumens:
-In STERRAD® 200 Sterilization, process only stainless steel lumened instruments of 3mm diameter or larger and a length up to 400 mm.
-In STERRAD NX standard cycle, process stainless steel lumened instruments of 2mm diameter or larger and up to 400 mm in length.
-In STERRAD NX advanced cycle, process stainless steel lumened instruments of 1mm diameter or larger and up to 500 mm in length and porous lumens (flexible endoscope) of 1mm diameter or larger and up to 850 mm in length.
-In Pre-vacuum Steam Flash Sterilization, process stainless steel lumened instruments of 2mm diameter or larger and a length of up to 400 mm as well as porous lumens of 3mm diameter or larger and a length up to 400 mm.
-In Ozone 125L Sterilization, process stainless steel lumened instruments of 3mm diameter or larger and a length up to 470 mm.

The attached tables identify which products with disposable filter may be sterilized in the respective sterilization cycles.

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

Sheila A. Murphy MD

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

510(k) Number: K080558

SteriTite Universal Container System Compatibility Table in Pre-vacuum flash w/ paper filter

Part Number	Description	Pre-vacuum flash w/ paper filter
SC03M	3" high Endo mini-size w/ solid base	X
SC03MG	3" high Endo mini-size w/ perforated base	X
SC03Q	3" high Endo mid-size w/ solid base	X
SC03QG	3" high Endo mid-size w/ perforated base	X
SC04F	4" high Full-size w/ solid base	X
SC04FG	4" high Full-size w/ perforated base	X
SC04H	4" high Half -size w/ solid base	X
SC04HG	4" high Half -size w/ perforated base	X
SC04Q	4" high Mid-size w/ solid base	X
SC04QG	4" high Mid-size w/ perforated base	X
SC06F	6" high Full-size w/ solid base	X
SC06FG	6" high Full-size w/ perforated base	X
SC06H	6" high Half -size w/ solid base	X
SC06HG	6" high Half -size w/ perforated base	X
SC06Q	6" high Mid-size w/ solid base	X
SC06QG	6" high Mid-size w/ perforated base	X
SC08F	8" high Full-size w/ solid base	X
SC08FG	8" high Full-size w/ perforated base	X
SC08H	8" high Half -size w/ solid base	X
SC08HG	8" high Half -size w/ perforated base	X
SC08Q	8" high Mid-size w/ solid base	X
SC08QG	8" high Mid-size w/ perforated base	X

SteriTite Universal Container System Compatibility Table Ozone 125L w/ paper & polypropylene disposable filter

Part Number	Description	Ozone 125L w/ paper or polypropylene disposable filter
SC03M	3" high Endo mini-size w/ solid base	X
SC03MG	3" high Endo mini-size w/ perforated base	X
SC03Q	3" high Endo mid-size w/ solid base	X
SC03QG	3" high Endo mid-size w/ perforated base	X
SC04F	4" high Full-size w/ solid base	X
SC04FG	4" high Full-size w/ perforated base	X
SC04H	4" high Half -size w/ solid base	X
SC04HG	4" high Half -size w/ perforated base	X
SC04Q	4" high Mid-size w/ solid base	X
SC04QG	4" high Mid-size w/ perforated base	X
SC06F	6" high Full-size w/ solid base	X
SC06FG	6" high Full-size w/ perforated base	X
SC06H	6" high Half -size w/ solid base	X
SC06HG	6" high Half -size w/ perforated base	X
SC06Q	6" high Mid-size w/ solid base	X
SC06QG	6" high Mid-size w/ perforated base	X
SC08F	8" high Full-size w/ solid base	X
SC08FG	8" high Full-size w/ perforated base	X
SC08H	8" high Half -size w/ solid base	X
SC08HG	8" high Half -size w/ perforated base	X
SC08Q	8" high Mid-size w/ solid base	X
SC08QG	8" high Mid-size w/ perforated base	X

SteriTite Universal Container System Compatibility in STERRAD 200 w/ polypropylene disposable filter

Part Number	Description	STERRAD 200 w/ polypropylene disposable filter
SC03MG	3" high Endo mini-size w/ perforated base	X
SC03QG	3" high Endo mid-size w/ perforated base	X
SC04FG	4" high Full-size w/ perforated base	X
SC04HG	4" high Half-size w/ perforated base	X
SC04QG	4" high Mid-size w/ perforated base	X
SC06FG	6" high Full-size w/ perforated base	X
SC06HG	6" high Half-size w/ perforated base	X
SC06QG	6" high Mid-size w/ perforated base	X
SC08FG	8" high Full-size w/ perforated base	X
SC08HG	8" high Half-size w/ perforated base	X
SC08QG	8" high Mid-size w/ perforated base	X

Note: Part number with suffix "G" signifies perforated bottom container, which must be used with non-woven Polypro filter for STERRAD Sterilization.

SteriTite Universal Container System Compatibility in STERRAD NX w/ polypropylene disposable filter

Part Number	Description	STERRAD NX w/ polypropylene disposable filter
SC03MG	3" high Endo mini-size w/ perforated base	X
SC03QG	3" high Endo mid-size w/ perforated base	X
SC04FG	4" high Full-size w/ perforated base	X
SC04HG	4" high Half-size w/ perforated base	X
SC04QG	4" high Mid-size w/ perforated base	X

Note: For STERRAD NX Sterilization only the 3" high and 4" high containers can be used due to STERRAD NX chamber size

MediTray Products Compatibility Table

MEDITRAY PRODUCT	STERRAD 200	STERRAD NX	Ozone 125L	Pre-vacuum flash
Baskets	X	X	X	X
Trays	X	X	X	X
Insert Boxes	X	X	X	X
Metal Brackets	X	X	X	X
Metal Partitions	X	X	X	X
Posts	X	X	X	X
Silicone Brackets	X	X	X	X
Racks	X	X	X	X
Stringers	X	X	X	X