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5. 510(K) Summary of Safety and Effectiveness

SteriTite Universal Container System with MediTray Products for STERRAD 100NX

510(k) Number (if known): K110682

Date Prepared: 2/24/2011

Company Name: Case Medical, Inc.
19 Empire Blvd
South Hackensack, NJ 07606

Contact: Tania Lupu
Phone: 201-313-1999 ext.229
Fax: 201-373-9090
Email: tlupu@casemed.com

Trade Name: *SteriTite® Universal Container System* & *MediTray* Products

Common Name: Sterilization container with disposable filter.

Regulation number: 880.6850

Classification name: Sterilization Wrap

Class of Device: Class II device

Product Code: 80FRG

Review Panel: General Hospital

Establishment Registration Number: 2248608

5.1 Substantial Equivalence:

Case Medical believes that the SteriTite universal container system is substantially equivalent to:

- SteriTite® universal container system -anodized- previously cleared for STERRAD NX, 510(K) #K080558.
- Aesculap® SterilContainer S non-anodized previously cleared for STERRAD 100NX, 510(k) K093493.

5.2 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 for STERRAD 100NX has perforated base. The container is made out of anodized aluminum with passivated stainless steel hardware and silicone gaskets. Each filter retention plate secures a disposable filter for bacterial barrier filtration. Various instrument trays as well as stacked baskets and inserts including insert boxes, brackets, posts, partitions and racks provide instrument protection and secure devices for sterilization within the container.

5.3 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 and instrumentation to be sterilized, transported and stored by health care providers. The container consists of a perforated base and lid with filter retention plates, and disposable polypropylene filters. The SteriTite universal container system is compatible for use with STERRAD 100NX Sterilization (Standard and Flex cycles). The SteriTite container has been validated with stainless steel and porous lumens, inoculated product, insert boxes, multilevel tray systems and various inserts including brackets, posts and partitions. The container may be used for sterilization of medical devices including full instrument sets and mixed loads.

SteriTite universal container system is recommended to be used for sterilization of surfaces and lumens:

- In STERRAD 100NX Standard cycle, process stainless steel lumens instruments of 0.7 mm diameter or larger and up to 500 mm in length.
- In STERRAD 100NX Flexible cycle, process flexible endoscopes, PE/PTFE Lumen instruments of ≥1.2 mm x ≤835 mm.

120 days of real time Shelf life testing with handling events has been conducted for SteriTite containers after STERRAD 100NX Sterilization.

Reuse testing was performed after 501 STERRAD 100NX Standard cycles.

The following tables identify which products with disposable filter may be sterilized in each (Standard and Flex) STERRAD 100NX sterilization cycle.

Table 1. SteriTite Universal Container System in STERRAD 100NX Standard Cycle

Part Number	Description	Total Loaded container weight (Lbs)
SC04FG	4" high Full-size w/ perforated base	22
SC06FG	6" high Full-size w/ perforated base	22
SC08FG	8" high Full-size w/ perforated base	22
SC04QG	4" high Mid-size w/ perforated base	19
SC06QG	6" high Mid-size w/ perforated base	19
SC08QG	8" high Mid-size w/ perforated base	19
SC04HG	4" high Half-size w/ perforated base	14
SC06HG	6" high Half-size w/ perforated base	14
SC08HG	8" high Half-size w/ perforated base	14
SC02NG	2" high mini long - w/ perforated base	10
SC03NG	3" high mini long size w/ perforated base	10
SC02MG	2" high mini-size w/ perforated base	6
SC03MG	3" high mini-size w/ perforated base	6
SC04MG	4" high mini-size w/ perforated base	6

Note: SteriTite Containers have been validated with 10 stainless steel lumens.

Table 2. SteriTite Universal Container System in STERRAD 100NX Flex Cycle

Part Number	Description	Total Loaded container weight (Lbs)
SC04FG	4" high Full-size w/ perforated base	16
SC06FG	6" high Full-size w/ perforated base	16
SC08FG	8" high Full-size w/ perforated base	16
SC04QG	4" high Mid-size w/ perforated base	16
SC06QG	6" high Mid-size w/ perforated base	16
SC08QG	8" high Mid-size w/ perforated base	16
SC04HG	4" high Half-size w/ perforated base	16
SC06HG	6" high Half-size w/ perforated base	16
SC08HG	8" high Half-size w/ perforated base	16
SC02NG	2" high mini long - w/ perforated base	10
SC03NG	3" high mini long size w/ perforated base	10
SC02MG	2" high mini-size w/ perforated base	6
SC03MG	3" high mini-size w/ perforated base	6
SC04MG	4" high mini-size w/ perforated base	6

Note: SteriTite containers have been validated with 1 flexible lumened device plus inserts per container.

Table 3. Meditray Products Compatibility

MediTray Products	STERRAD 100NX
Baskets	X
Trays	X
Insert Boxes	X
Metal Brackets	X
Metal Partitions	X
Posts	X
Silicone Brackets	X
Racks	X
Stringers	X

Table 4. SteriTite Accessories Compatibility

SteriTite Accessories	STERRAD 100NX
SCF02 Round filter	X
SCFM02 Rectangular filter	X
SCS01W Tamper Evident Seals	X
SCLH2O23 Load Card Large	X
SCLH2O24 Load Card Small	X

5.4 Technological Characteristics (compared to the predicate(s)):

The SteriTite container system for STERRAD 100NX Sterilization is the same SteriTite container previously cleared for steam, STERRAD 100, 100S, 200, NX, as well as EtO, Ozone and Hydrogen Peroxide (V-pro1) Sterilization. Case Medical's SteriTite universal container and MediTray products are compatible with STERRAD 100NX (Standard and Flex cycles). All containers are of equivalent sizes, have gasketed lids with latching mechanism and offer tamper evident features and external indicator as predicate devices. The SteriTite sealed container in this submission is the same container previously cleared.

5.5 Performance Data:

All required testing per "Draft Guidance for the Preparation of Premarket Notifications 510(k)'s" was completed. The SteriTite universal container system with MediTray products were fully validated for STERRAD 100NX Sterilization (Standard and Flex cycles). The validation testing was conducted at qualified independent laboratories in accordance with FDA guidance and available AAMI standards.

5.5 Conclusion:

All data presented demonstrate Substantial Equivalence to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

JUL - 1 2011

Ms. Tania Lupu
QA/QC Director
Case Medical, Incorporated
19 Empire Boulevard
South Hackensack, New Jersey 07606

Re: K110682
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: KCT
Dated: May 10, 2011
Received: June 3, 2011

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,

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

4. Indication for Use Statement

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Reuse testing was performed after 501 STERRAD 100NX Standard cycles.

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 In Vitro Diagnostic Devices (OIVD)

Claire S. Marshall for Elizabeth Claverie-Williams

Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety

510(k) K110682

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