510(k) SUMMARY
(21 C.F.R.§ 807.92)

K030853

MAR 21 2003

Case Medical, Inc.
65 Railroad Avenue
Ridgefield, NJ 07657
TEL: 888.227.CASE
FAX: 201-313-9090

NON-CONFIDENTIAL SUMMARY OF SAFETY AND EFFECTIVENESS

Device trade or proprietary name:	*SteriTite®* perforated base rigid reusable sterilization container system with *SCF02*- polypropylene non-woven Disposable Filter
Device Common/ usual name:	Sterilization rigid reusable case with disposable filter.
Classification name:	Sterilization Wrap
Class of Device:	Class II device, product code 80FRG
Predicate Device:	*SteriTite®* System *previously approved under K991023*
Official contact:	Marcia Frieze, CEO, ext. 25

DEVICE DESCRIPTION

The *SteriTite®* Rigid Container System consists of a family of rigid containers that provide an effective sterilization packaging method for operating room instruments. The *SteriTite®* perforated base containers include a vented base and a vented lid with filter retention plates. The *SteriTite®* unit consists of an anodized aluminum sealed case with a microbial barrier filtration system that allows effective penetration by the sterilant. The *SteriTite®* perforated base containers with baskets have been validated for surfaces and lumens in STERRAD 100S Sterilization. For STERRAD 100 and 100S Sterilization each stainless steel filter retention plate secures a disposable round non-woven polypropylene disposable bacterial filter. Silicone gaskets are permanently attached to the filter retention plates and lid with silicone adhesive. A stainless steel latching mechanism with handles on both ends secures the lid to the base and provides a method to incorporate tamperproof disposable locks.

The disposable filter # SCF02 is a nonwoven polypropylene material .

INDICATIONS FOR USE

The perforated base containers are part of a line of the *SteriTite®* Reusable Rigid Sterilization Container system. The *SteriTite®* perforated base containers have been validated for use in STERRAD 100S Sterilization under the following conditions. They are intended to be used for the sterilization of surgical instruments and devices in STERRAD 100S Sterilization for a hospital or other health care facilities.

Review the sterilizer manufacturer's Instructions for Use for specific information as to the limitations of instrumentation specifications and material compatibility. Review the

SteriTite® labeling as to the limitations in regard to using a sealed container system in STERRAD 100S Sterilization.

- **Caution:** In STERRAD 100S Sterilization use only perforated bottom *SteriTite®* containers.

- **Caution:** In STERRAD 100S Sterilization use only nonwoven polypropylene disposable filters.
- **Caution:** In STERRAD 100S Sterilization *do* not use materials made of cellulose (paper filters and cotton) with *SteriTite®* perforated bottom containers.
- **Caution:** In STERRAD 100S Sterilization use only lumened instruments of 3mm or larger and a length of up to 400 mm.

SUMMARY OF PERFORMANCE TESTING

The SteriTite® Container with non-woven polypropylene filter containing instrument basket and load was validated under half cycle conditions in triplicate in the STERRAD 100S System. The efficacy of the Case Medical container was clearly demonstrated for blades and lumens using the overkill method. Containers in combination of 10" in total height or 8" high for any one container were tested and found to be efficacious. The same combinations were previously validated in the prior 510k K991023 for the STERRAD 100 System.

Additional studies were performed to demonstrate the effects of sterilant volume on microbial inactivation kinetics.

Reuse testing of the container and inserts was accomplished previously for100 cycles in the STERRAD 100 Sterilization System. The product proved to be effective and compatible upon completion. Equivalency of the sealed container to a wrapped instrument tray was demonstrated.

The SteriTite® Container was independently tested according the following standards for its performance in STERRAD 100S Sterilization. ASP conducted testing in accordance with the following U.S. and international standards:

AAMI ST 34 " Guideline for the use of ethylene oxide and steam biological indicators in industrial sterilization processes."

ANSI/AAMI ST33-1996 *" Good Hospital Practice: Guidelines for the Selection and Use of Reusable Rigid Sterilization Container Systems."*
ANSI/AAMI/ISO 11134-1994 *"Sterilization of health care products-Requirements for validation and routine control-Industrial moist heat sterilization."*
European Standard, pr EN 868-8, second draft May 1995. *"Packaging materials and systems for medical devices which are to be sterilized. Part 8: Re-usable sterilization containers – Requirements and test methods."*

COMPARISON: STERITITE PERFORATED BASE CONTAINERS TO SPUNGUARD WRAP *

USE	SteriTite Perforated Container with polypropylene filter STERRAD 100	SteriTite Perforated Container with polypropylene filter STERRAD 100S	Spunguard wrap
Indicated for holding instruments to be sterilized and stored	YES	YES	YES
Intended to be reused	YES	YES	NO
Methods of sterilization:			
Prevacuum steam	YES	YES	YES
Gravity steam	YES	YES	YES
STERRAD 100Sterilization	YES FOR BLADES, YES FOR LUMENS		YES FOR BLADES. YES FOR LUMENS
STERRAD 100S Sterilization		YES FOR BLADES, YES FOR LUMENS	YES FOR BLADES. YES FOR LUMENS
DESIGN			
Incorporates a filter / wrap system to permit entry of sterilant agent and prevent microbial migration during storage	YES	YES	YES
MATERIALS: container /basket **Filter / wrap**	Aluminum, SS, silicone Polypropylene	Aluminum, SS, silicone Polypropylene	 Polypropylene
PERFORMANCE STANDARDS/ SPECIFICATIONS			
AAMI ST33 Standard testing requirements			
3.2. Permits transfer of contaminated materials	YES	YES	YES
3.3.1 Removable filter assembly disassembles	YES	YES	NO
3.3.4 Labeling	YES	YES	YES
3.4 –3.5 Decontamination instructions	YES	YES	YES
3.6-4.2 Instructions for inspections	YES	YES	YES
6.2.5 Sterility maintenance-discussed in labeling	YES	YES	YES

6.3 User responsibilities listed in labeling	YES	YES	YES
7.3.1 Routine inspection in labeling	YES	YES	YES
VALIDATION TESTING			
Testing performed using "overkill" approach	YES	YES	YES
STERRAD® half-cycle parameters	YES	YES	YES
STERRAD® half-cycle parameters - incremental	YES	YES	YES
Load	STU load	STU load	STU load
TESTING ORGANISM			
Bacillus Stearothermophilus	YES	YES	YES
Inoculated spore carriers with 1×10^6 B. Stearothermophilus	YES	YES	YES
INOCULATED BLADES under half-cycle conditions	YES	YES	YES
INOCULATED LUMENS under half cycle conditions with 3mm DIA x 400mm	YES	YES	YES
OCCLUSION under half-cycle conditions –		YES	YES

* Note: Each container and wrap contained STU load with blades and lumens. For STERRAD 100S occlusions were added.

1. Polypropylene Nonwoven Filter: Testing performed demonstrated adequate sterilant penetration as well as barrier properties when used with the *SteriTite*® rigid reusable container system in the STERRAD 100 and 100S Sterilization process.

BIOCOMPATIBILITY

As stated previously in the cleared 510k # K991023 Kimguard was extensively tested in the standard spectrum of biocompatibility testing.
This included USP Acute Systemic Toxicity, Human Patch Test and Guinea Pig Sensitization Test. All test results were negative.
The Biocompatibility validation of the SteriTite container materials was addressed by ASP reference to "Toxicity of Sterilant and Process By-Products" in which aluminum, silicone, stainless steel, polypropylene were tested and found to be non-cytoxic and found to be compatible with the STERRAD System. This was included in the STERRAD 100 510(k). The toxicity of the sterilant has not changed.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 21 2003

Ms. Marcia Frieze
CEO
Case Medical, Incorporated
65 Railroad Avenue
Ridgefield, New Jersey 07657

Re: K030853
Trade/Device Name: SteriTite® Perforated Base Rigid Sterilization Container System: SC04HG, SC06HG, SC08HG, SC04QG, SC06QG, SC08QG, SC04FG, SC06FG, SC08FG, SC03MG, SC03QG & PolyPro™ Disposable Filter # SCF02
Regulation Number: 880.6850
Regulation Name: Sterilization Wrap
Regulatory Class: II
Product Code: FRG
Dated: March 17, 2003
Received: March 18, 2003

Dear Ms. Frieze:

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.

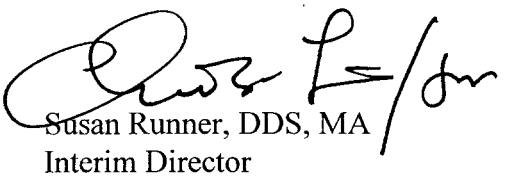
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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 Office of Compliance at (301) 594-4618. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). 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) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,



Susan Runner, DDS, MA
Interim Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number : K030853

Device Name : SteriTite ® Perforated Base Rigid Sterilization Container System: SC04HG, SC06HG, SC08HG, SC04QG, SC6QG, SC08QG, SC04FG, SC06FG, SC08FG, SC03MG, SC03QG & PolyPro™ Polypropylene Disposable Filter # SCF02 with MediTray product.

INDICATIONS FOR USE

The perforated base containers are part of the *SteriTite®* Reusable Rigid Sterilization Container system. Product # of intended device	DESCRIPTION
SC04HG	4" High Half size case perforated bottom
SC06HG	6"High Half size case perforated bottom
SC08HG	8"High Half size case perforated bottom
SC04QG, Rev. B	4"High Mid-size case perforated bottom
SC06QG, Rev. B	6"High Mid-size case perforated bottom
SC08QG,Rev.B	8"High Mid-size case perforated bottom
SC04FG	4"High Full-size case perforated bottom
SC06FG	6"High Full-size case perforated bottom
SC08G	8"High Full-size case perforated bottom
SC03MG	3"High Mini-size case perforated bottom
SC03QG	3"High ¾ Mini-size case perforated bottom

The *SteriTite®* perforated base containers using polypropylene nonwoven Disposable Filter # SCF02 may be used for the sterilization of surgical instruments in STERRAD 100S Sterilization for a hospital or other health care facilities.

- After each sterilization cycle the filters must be discarded.
- Before each sterilization cycle use new filters.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

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

510(k) Number_____

Description Use_____ OR Over- The-Counter Use_____

(Per 21 CFR 801.109)

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

510(k) Number: K030853

(Optional Format 1-2-96)