JAN 27 2000

510(k) SUMMARY K991023
(21 C.F.R.§ 807.92)

Case Medical, Inc.
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Ridgefield, N.J. 07657
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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:	Spunguard wrap/*SteriTite*® Container System
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 steam previously cleared K960738. In addition the *SteriTite*® perforated base containers have been validated for blades and lumens in STERRAD 100 Sterilization. For STERRAD 100 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 polypropylene non-woven disposable filter # SCF02 is cut from Kimguard ® wrap. Kimguard ® wrap is manufactured from a hydrophobic nonwoven polypropylene material as is Spunguard wrap, the previously cleared device.

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 100 Sterilization under the following conditions. They are intended to be used for the sterilization of surgical instruments and devices in STERRAD 100 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 100 Sterilization.

- **Caution:** In STERRAD 100 Sterilization use only perforated bottom *SteriTite*® containers.
- **Caution:** In STERRAD 100 Sterilization use only nonwoven polypropylene disposable filters.
- **Caution:** In STERRAD 100 Sterilization *do* not use materials made of cellulose (paper filters and cotton) with *SteriTite*® perforated bottom containers.
- **Caution:** In STERRAD 100 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 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.

Further, in order to demonstrate adequate sterilant penetration, the SteriTite® Container was validated for efficacy in the STERRAD System by comparing it against a tray wrapped in Spunguard, as the predicate. This study was done in triplicate and conducted in increments below the half cycle in diffusion time and concentration of sterilant. The objective was to compare a lidded container with basket versus a wrapped tray.

Reuse testing of the container and inserts for 100 cycles in the STERRAD 100 Sterilization System proved to be effective and compatible upon completion.

1. The SteriTite® Container was independently tested according the following standards for its performance in STERRAD 100 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 polyproplyene filter	Spunguard wrap
Indicated for holding instruments to be sterilized and stored	YES	YES
Intended to be reused	YES	NO
Methods of sterilization:		
Prevacuum steam	YES	YES
Gravity steam	YES	YES
STERRAD 100 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
MATERIALS: container /basket Filter / wrap	Aluminum, SS, silicone Polypropylene	Aluminum, SS, silicone Polypropylene
PERFORMANCE STANDARDS/ SPECIFICATIONS		
AAMI ST33 Standard testing requirements		
3.2. Permits transfer of contaminated materials	YES	YES
3.3.1 Removable filter assembly disassembles	YES	NO
3.3.4 Labeling	YES	YES
3.4 –3.5 Decontamination instructions	YES	YES
3.6-4.2 Instructions for inspections	YES	YES
6.2.5 Sterility maintenance-discussed in labeling	YES	YES
6.3 User responsibilities listed in labeling	YES	YES
7.3.1 Routine inspection in labeling	YES	YES
VALIDATION TESTING		
Testing performed using "overkill" approach	YES	YES
STERRAD® half-cycle parameters	YES	YES
STERRAD® increments below half-cycle parameters	YES	YES
Incremental Testing –diffusion time	10 minute kill	10 minute kill
Incremental Testing –diffusion H2O2	720 µl	360 µl
Load	STU load + basket	STU load + basket
TESTING ORGANISM		
Bacillus stearothermophilus	YES	YES
Inoculated spore carriers with 1 x 10^6 B. stearothermophilus	YES	YES
INOCULATED BLADES under half-cycle conditions	YES	YES
INOCULATED LUMENS under half cycle conditions with 3mm DIA x 400mm	YES	YES

* Note: Each container and wrap contained STU load with blades and lumens.

2. 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 Sterilization process.

The previously cleared and tested wrap was Spunguard. Kimguard is the selected filter material and is currently used with Genesis and Aesculap containers for steam sterilization. See Spunguard/Kimguard Equivalence Chart below.

BIOCOMPATIBILITY

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 noncytoxic and found to be compatible with the STERRAD System. This was included in the STERRAD 50 510(k). The toxicity of the sterilant has not changed. See Attachment # P-1199.

COMPARISON TO LEGALLY MARKETED DEVICE

SPUNGUARD / KIMGUARD EQUIVALENCE

	SPUNGUARD WRAP	**KIMGUARD WRAP**
Construction	3 layer construction	3 layer construction
Tear / Puncture resistance	Tear resistance	Tear resistance
Hydrophobic properties	Resist penetration of particles and liquids.	Resist penetration of particles and liquids.
Material	100% non-woven Polypropylene	100% non-woven Polypropylene
Drapeability	Drapeable, soft	Drapeable, soft
Weights	Super duty Heavy duty Regular	Ultra Heavy duty Midweight Regular
STERRAD penetration study	Efficacious - Validated by ASP	Efficacious - Validated by ASP
Event related sterility maintenance study*	Higher sterility assurance than Muslin Spun.:1.1% / Mus.22.8%	Higher sterility assurance than Muslin or Spunguard. Excellent. Kim.:0% / Mus.:10%

*The weight of Spunguard and Kimguard used for the above studies was the weight posing the greatest challenge to sterilant penetration or sterility maintenance.

Reference Kimberly-Clark Spunguard Sterilization Wrap Technical Data and Kimguard Sterilization Wrap Technical Data.

BARRIER PROPERTIES

For KIMGUARD® bacterial filtration efficiency tests refer to equivalence Spunguard / Kimguard chart. Filtration Efficiency is equal for both. Water resistance is better in Kimguard®.

	SPUNGUARD WRAP	KIMGUARD WRAP
Filtration Efficiency / Bacteria per 1000 dry spore penetration	3-heavy duty	3-regular
Water Resistance / water repelled before leakage cms.	44cms.-heavy duty	55cms-regular

PHYSICAL AND MECHANICAL SPECIFICATIONS

For KIMGUARD® physical and mechanical properties refer to the following equivalence Spunguard / Kimguard chart.

Strength: better in Spunguard. Not important due to the offset hole design of the SteriTite container.

Resistance to Linting is better in KIMGUARD®

	SPUNGUARD WRAP	KIMGUARD WRAP
Strength : Tensile load / lbs.	18-heavy duty	14.5-regular
Peak energy absorption / in-lbs.	20-heavy duty	14.5-regular
Resistance to Linting / no. of lint particles >10μ	28-heavy duty	21-regular

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 27 2000

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

Re: K991023
Trade Name: SteriTite® Perforated Base Rigid Reusable Sterilization Container System With SCF02 - Polypropylene Non-Woven Disposable Filter
Regulatory Class: II
Product Code: FRG
Dated: November 23, 1999
Received: November 23, 1999

Dear Ms. Frieze:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to 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). 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 (Premarket Approval), 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 895. A substantially equivalent determination assumes compliance with the Good Manufacturing Practice for Medical Devices: General (GMP) regulation (21 CFR Part 820) and that, through periodic GMP inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any

obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 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 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4692. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

Timothy A. Ulatowski
Director
Division of Dental, Infection Control
and General Hospital Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number : K991023

Device Name : SteriTite ® Perforated Base Rigid Sterilization Container System: *SC04HG, SC06HG, SC08HG, SC04QG, SC6QG, SC08QG, SC04FG, SC06FG, SC08FG &* Kimguard ® Disposable Filter # SCF02

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
SC08FG	8"High Full-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 100 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 K991023

Description Use_____ OR Over- The-Counter Use ✓

(Per 21 CFR 801.109) (Optional Format 1-2-96)

(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number _____