K023614

APR 0 7 2003

510(k) SUMMARY
(21 C.F.R.§ 807.92)

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® rigid reusable sterilization container system.
Device Common/ usual name:	Sterilization, rigid reusable case.
Establishment registration number:	2248608
Classification name:	Sterilization Wrap
Class of Device:	Class II device, product code 80FRG
Predicate	Genesis™ - 510k # K012931
Official contact:	Marcia A. Frieze, CEO, 201-313-1999 ext. 225

INTENDED USE

The SteriTite® container system is designed for use in hospitals and health care facilities to contain medical devices for sterilization, storage, transportation, and aseptic presentation of contents.

It is intended to be used to sterilize medical devices including surfaces and lumens in steam, gas (EO) and gas plasma (STERRAD Sterilization). The SteriTite container is designed to maintain sterility of the contents until it is used.

DEVICE DESCRIPTION

The SteriTite® container system consists of a family of rigid reusable sealed containers that provide an effective sterilization packaging method for medical devices. Cases and lids are interchangeable. A part number and lot number identify each component of the container, including lid, base, retainer/valve plate and insert basket or tray.

The SteriTite system is designed for sterilant penetration through vents/perforations in the lid and in perforated bottom models in the base of SteriTite sealed containers as well. MediTray case/trays, baskets and insert boxes may be placed within sealed containers or wrapped.

EQUIVALENCE STATEMENT FOR STERITITE® CONTAINER WITH FILTER IN EO STERILIZATION

Case Medical, Inc.'s SteriTite filtered container is substantially equivalent to the Genesis (510k # K012931) container with disposable filter.

Comparison of SteriTite® Rigid Reusable Containers with disposable filter to Predicate

PROPERTIES/ SPECIFICATIONS	STERITITE® CASE W/ FILTER	GENESIS CASE W/ FILTER
Indicated for containing instruments to be sterilized in EO, and be transported	YES	YES
Intended to be reused	YES	YES
Closed System	YES	YES
Sealed	YES	YES
DESIGN		
Incorporates a filter system to permit entry of sterilant agent	YES	YES
Incorporates a filter system to prevent microbial migration during transport	YES	YES
MATERIALS		
Container Filter	Aluminum, SS, silicone Disposable filter	Aluminum, SS, silicone Disposable filter
PERFORMANCE STANDARDS		
Conformance to AAMI ST33 Standard testing requirements	YES	YES
VALIDATION TESTING		
Pre-vacuum steam	YES	YES
Gravity Displacement steam	YES	YES
EO Sterilization	YES (solid and perforated bottom containers)	YES (perforated bottom containers)
STERRAD Sterilization	YES	YES
Load	STU load up to 22 lbs.	Up to 11 Lbs.
Sterility Maintenance – Barrier properties	Event Related Sterility Maintenance: 90-day real time w/weekly handling events. 30-day real time with daily handling events	Event Related Sterility Maintenance: 180-day (30-day) real time

PROPERTIES/ SPECIFICATIONS	STERITITE® CASE W/ FILTER	GENESIS CASE W/ FILTER
Aeration Time	12 Hours	24 Hours
TEST organism/inoculated product		
Inoculated spore carriers with 1 x 10^6 Bacillus Subtilis var. niger	YES	YES
INOCULATED BLADES	YES	YES
INOCULATED LUMENS	YES – 2.2mm diameter metal	YES - 3mm diameter metal
INOCULATED NYLON	YES	N/A
INOCULATED SILICONE	YES	N/A
INOCULATED RADEL	YES -	N/A

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 0 7 2003

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

Re: K023614
Trade/Device Name: SteriTite® Rigid Sterilization Container System with MediTray Products
Regulation Number: 880.6850
Regulation Name: Sterilization Wrap
Regulatory Class: II
Product Code: FRG
Dated: January 6, 2003
Received: January 7, 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

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: K023614

Device Name: SteriTite® Rigid Sterilization Container System with MediTray Products

INDICATIONS FOR USE:

The SteriTite container system and MediTray product is intended to be used to contain medical devices for sterilization, storage, transportation and aseptic presentation of contents in health care facilities. This includes sterilization of surfaces and lumened dev in EO. Metal lumens 2.2mm diameter or larger and length up to 45.7 cm and porous (silicone) lumened devices 3 mm diameter or larger and length up to 40 cm were validated. The SteriTite container is designed to maintain sterility of the contents until it is used.

(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) (Optional Format 1-2-96)

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

510(k) Number K023614