MAY - 9 2003

Case Medical, Inc.®

65 Railroad Ave • Ridgefield, NJ 07657 • 800-639-3264 • 201-313-1978 • Fax 201-313-9090

510(k) SUMMARY
(21 C.F.R.§ 807.92) K022978

NON-CONFIDENTIAL SUMMARY OF SAFETY AND EFFECTIVENESS

SteriTite Rigid Sterilization Container System with FlashTite valve plate(s) and MediTray Products

Manufacturer:	Case Medical, Inc.
Date Summary Prepared:	May 6, 2003
Device trade or proprietary name:	*SteriTite®* container with *FlashTite* valve plate(s) and MediTray Products
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 for Flash Sterilization:	*SteriTite® previously cleared under K960738 & K974638. FlashPak K871202. FlashGuard K841669*
Predicate for MediTray Products:	*Sterilization Cassettes, K962545*
Official contact:	Marcia Frieze, CEO, 201-313-1999 ext. 225

INTENDED USE:

The SteriTite® containers with FlashTite® valve plate(s) are intended to be used in conjunction with MediTray basic tray for the flash sterilization of one instrument or instrument set.
The SteriTite container system with MediTray product are intended to be used to contain medical devices for steam sterilization. The full line of MediTray products is intended for complex customization in pre-vacuum steam sterilization.
MediTray basic trays are intended to be used in the sealed container for sterilization in steam pre-vacuum and gravity sterilization. MediTray products may be used separately for sterilization when wrapped in FDA cleared medical grade wrappers.
The MediTray products include case/trays with lid and base, insert boxes, cassettes, trays, baskets, instrument racks, silicone mats, brackets, posts, and partitions.

DEVICE DESCRIPTION:

The SteriTite® container system consists of the SteriTite line of rigid reusable containers with an additional option of a FlashTite valve plate(s). The line features an assortment of container designs and sizes.
The MediTray product line includes instrument baskets, trays, and case/trays (incorporating a lid and base), organizing insert boxes, cassettes, trays, baskets, instrument racks, silicone mats, brackets, posts, and partitions designed to contain medical devices within sealed containers or to be wrapped.
SteriTite Containers with FlashTite valve plate(s) and MediTray products may be stacked.

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Substantial equivalence:

The Case Medical, Inc.'s *SteriTite®* container with *FlashTite* valve plate(s) is substantial equivalent to the *Flashpak Container System* by Riley Medical and *Flashguard Container System* by Sparco Inc. in that the:

- Intended use is the same.
- Performance attributes are the same.

The Case Medical, Inc.'s MediTray Products line is substantial equivalent to the *Sterilization Cassettes* by Sterilization Cassette Systems, Inc. in that the:

- Intended use is the same.
- Performance attributes are the same.

Summary of testing:

Sterilization Performance studies were conducted at independent laboratories for the SteriTite Reusable Rigid Container with FlashTite valve plate(s). All tests were conducted with containerized MediTray as well as MediTray products wrapped. All acceptance criteria were met. Results demonstrate that the product is in compliance with established standards and is validated for its intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY - 9 2003

Ms. Marcia A. Frieze
CEO
Case Medical, Incorporated
65 Railroad Avenue
Ridgefield, New Jersey 07657-0402

Re: K022978
Trade/Device Name: SteriTite® Rigid Sterilization Container System with FlashTite® valve plate (s) & MediTray Products
Regulation Number: 21 CFR 880.6850
Regulation Name: Sterilization Wrap
Regulatory Class: II
Product Code: FRG
Dated: February 13, 2003
Received: February 13, 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: K022978

Device Name: SteriTite® Rigid Sterilization Container System with FlashTite® valve plate(s) & MediTray Products

INDICATIONS FOR USE:

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The MediTray products include case/trays with lid and base, insert boxes, cassettes, trays, baskets, instrument racks, silicone mats, brackets, posts, partitions.

(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_____

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

510(k) Number: K 022978