DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Ms. Tania Lupu
Quality Assurance – Quality Control Director
Case Medical, Incorporated
65 Railroad Avenue
Ridgefield, New Jersey 07657-0402

DEC 0 5 2008

Re: K080558
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: FRG
Dated: November 13, 2008
Received: November 28, 2008

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.

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 Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. 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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Chiu S. Lin, Ph. D
Division Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): _____

Device Name: SteriTite Universal Container System and MediTray products

Indications for Use:

The SteriTite universal container system with MediTray products is a reusable sterilization container system used to enclose other medical devices, which are to be sterilized, transported and stored by a health care provider. The SteriTite container system is intended for use in STERRAD 200, STERRAD NX and Ozone 125L sterilizers, as well as the sealed containers are intended for pre-vacuum steam flash sterilization (270°F for 4 minutes). The container may be used for sterilization of medical devices including full instrument sets and mixed loads.

SteriTite Sealed Container system is recommended for surface and lumens:
-In STERRAD® 200 Sterilization, process only stainless steel lumened instruments of 3mm diameter or larger and a length up to 400 mm.
-In STERRAD NX standard cycle, process stainless steel lumened instruments of 2mm diameter or larger and up to 400 mm in length.
-In STERRAD NX advanced cycle, process stainless steel lumened instruments of 1mm diameter or larger and up to 500 mm in length and porous lumens (flexible endoscope) of 1mm diameter or larger and up to 850 mm in length.
-In Pre-vacuum Steam Flash Sterilization, process stainless steel lumened instruments of 2mm diameter or larger and a length of up to 400 mm as well as porous lumens of 3mm diameter or larger and a length up to 400 mm.
-In Ozone 125L Sterilization, process stainless steel lumened instruments of 3mm diameter or larger and a length up to 470 mm.

The attached tables identify which products with disposable filter may be sterilized in the respective sterilization cycles.

Prescription Use _____ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use ___v____ (21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Mark K. Murphy MD

(Division Sign-Off)

Division of Anesthesiology, General Hospital Infection Control, Dental Devices

510(k) Number: K080558

SteriTite Universal Container System Compatibility Table in Pre-vacuum flash w/ paper filter

Part Number	Description	Pre-vacuum flash w/ paper filter
SC03M	3" high Endo mini-size w/ solid base	X
SC03MG	3" high Endo mini-size w/ perforated base	X
SC03Q	3" high Endo mid-size w/ solid base	X
SC03QG	3" high Endo mid-size w/ perforated base	X
SC04F	4" high Full-size w/ solid base	X
SC04FG	4" high Full-size w/ perforated base	X
SC04H	4" high Half -size w/ solid base	X
SC04HG	4" high Half -size w/ perforated base	X
SC04Q	4" high Mid-size w/ solid base	X
SC04QG	4" high Mid-size w/ perforated base	X
SC06F	6" high Full-size w/ solid base	X
SC06FG	6" high Full-size w/ perforated base	X
SC06H	6" high Half -size w/ solid base	X
SC06HG	6" high Half -size w/ perforated base	X
SC06Q	6" high Mid-size w/ solid base	X
SC06QG	6" high Mid-size w/ perforated base	X
SC08F	8" high Full-size w/ solid base	X
SC08FG	8" high Full-size w/ perforated base	X
SC08H	8" high Half -size w/ solid base	X
SC08HG	8" high Half -size w/ perforated base	X
SC08Q	8" high Mid-size w/ solid base	X
SC08QG	8" high Mid-size w/ perforated base	X

SteriTite Universal Container System Compatibility Table Ozone 125L w/ paper & polypropylene disposable filter

Part Number	Description	Ozone 125L w/ paper or polypropylene disposable filter
SC03M	3" high Endo mini-size w/ solid base	X
SC03MG	3" high Endo mini-size w/ perforated base	X
SC03Q	3" high Endo mid-size w/ solid base	X
SC03QG	3" high Endo mid-size w/ perforated base	X
SC04F	4" high Full-size w/ solid base	X
SC04FG	4" high Full-size w/ perforated base	X
SC04H	4" high Half -size w/ solid base	X
SC04HG	4" high Half -size w/ perforated base	X
SC04Q	4" high Mid-size w/ solid base	X
SC04QG	4" high Mid-size w/ perforated base	X
SC06F	6" high Full-size w/ solid base	X
SC06FG	6" high Full-size w/ perforated base	X
SC06H	6" high Half -size w/ solid base	X
SC06HG	6" high Half -size w/ perforated base	X
SC06Q	6" high Mid-size w/ solid base	X
SC06QG	6" high Mid-size w/ perforated base	X
SC08F	8" high Full-size w/ solid base	X
SC08FG	8" high Full-size w/ perforated base	X
SC08H	8" high Half -size w/ solid base	X
SC08HG	8" high Half -size w/ perforated base	X
SC08Q	8" high Mid-size w/ solid base	X
SC08QG	8" high Mid-size w/ perforated base	X

SteriTite Universal Container System Compatibility in STERRAD 200 w/ polypropylene disposable filter

Part Number	Description	STERRAD 200 w/ polypropylene disposable filter
SC03MG	3" high Endo mini-size w/ perforated base	X
SC03QG	3" high Endo mid-size w/ perforated base	X
SC04FG	4" high Full-size w/ perforated base	X
SC04HG	4" high Half-size w/ perforated base	X
SC04QG	4" high Mid-size w/ perforated base	X
SC06FG	6" high Full-size w/ perforated base	X
SC06HG	6" high Half-size w/ perforated base	X
SC06QG	6" high Mid-size w/ perforated base	X
SC08FG	8" high Full-size w/ perforated base	X
SC08HG	8" high Half-size w/ perforated base	X
SC08QG	8" high Mid-size w/ perforated base	X

Note: Part number with suffix "G" signifies perforated bottom container, which must be used with non-woven Polypro filter for STERRAD Sterilization.

SteriTite Universal Container System Compatibility in STERRAD NX w/ polypropylene disposable filter

Part Number	Description	STERRAD NX w/ polypropylene disposable filter
SC03MG	3" high Endo mini-size w/ perforated base	X
SC03QG	3" high Endo mid-size w/ perforated base	X
SC04FG	4" high Full-size w/ perforated base	X
SC04HG	4" high Half-size w/ perforated base	X
SC04QG	4" high Mid-size w/ perforated base	X

Note: For STERRAD NX Sterilization only the 3" high and 4" high containers can be used due to STERRAD NX chamber size

MediTray Products Compatibility Table

MEDITRAY PRODUCT	STERRAD 200	STERRAD NX	Ozone 125L	Pre-vacuum flash
Baskets	X	X	X	X
Trays	X	X	X	X
Insert Boxes	X	X	X	X
Metal Brackets	X	X	X	X
Metal Partitions	X	X	X	X
Posts	X	X	X	X
Silicone Brackets	X	X	X	X
Racks	X	X	X	X
Stringers	X	X	X	X