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.

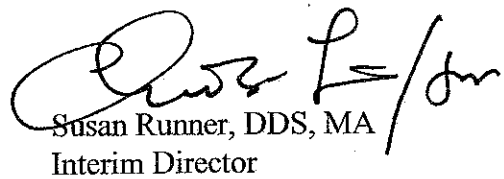
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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)

Chris S. Lin

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

510(k) Number: K030853

(Optional Format 1-2-96)