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 _____