DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY -6 1997

Ms. Tania Lupu
QA-QC Manager
Case Medical, Incorporated
65 Railroad Avenue
Ridgefield, New Jersey 07657

Re: K960738
Trade Name: Steritite Sealed Containers Models SC08F, SC08FG, SLOXF, SC06F, SC06FG, SCO4F, SCO4FG, SCO8Q, SC08QG, SLOXQ, SC06Q, SC06QG, SC04QG, SC08H, SC08HG, SLOXH, SCO6H, SCO6HG, SCO4H, SC04HG,
Regulatory Class: II
Product Code: KCT
Dated: March 21, 1997
Received: March 25, 1997

Dear Ms. Lupu:

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

510(k) Number (if known): K960738

Device Name: SteriTite™ Rigid Sterilization Container System

Indications For Use:

The SteriTite™ product line is a Reusable Rigid Sterilization Container system intended to be used for the sterilization of surgical instruments for a hospital or other health care institution.

(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 K960738

Prescription Use _____ OR Over-The-Counter Use X
(Per 21 CFR 801.109)

(Optional Format 1-2-96)