DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

JAN 2 4 2012

Ms. Tania Lupu
Quality Assurance, QC Director
Case Medical, Incorporated
19 Empire Blvd.
South Hackensack, New Jersey 07606

Re: K112904
Trade/Device Name: SteriTite® Universal Container System & MediTray Products
Regulation Number: 21 CFR 880.6850
Regulation Name: Sterilization Wrap
Regulatory Class: II
Product Code: FRG
Dated: January 5, 2012
Received: January 6, 2012

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to 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); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for Anthony Watson

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K112904

Indications for Use

510(k) Number (if known): __112904__

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 container consists of a perforated base and lid, with filter retention plates, and disposable polypropylene filters. The SteriTite container system is compatible for use with AMSCO V-PRO 1 Plus low temperature Sterilization System, Lumen and Non-lumen Cycle, and AMSCO V-PRO maX low temperature Sterilization System Lumen, Non-lumen and Flexible Cycle. The SteriTite container has been validated with stainless steel and porous lumens, inoculated product, insert boxes, multilevel tray systems and various inserts, including brackets, posts and partitions. The SteriTite container may be used for sterilization of medical devices, including full instrument sets and mixed loads.

- 30 days of real time shelf-life testing with handling events has been conducted for SteriTite containers after sterilization in Amsco V-PRO sterilization lumen cycle.
- Reuse testing: Material Compatibility was assessed after 100 cycles of AMSCO V-PRO 1 lumen cycles.

SteriTite Universal Container System is recommended for use in:

1. **V-PRO 1 Plus sterilizer in:**

- Non-lumen cycles to sterilize non-lumened instruments, including non-lumened rigid endoscopes and non-lumened hinged instruments, such as forceps or scissors.
- Lumen cycles to sterilize instruments with diffusion restricted areas, such as the hinged portion of forceps and scissors, and medical devices, including rigid endoscopes, with a single stainless steel lumen, with an inside diameter of 3mm or larger and a length of 400mm or shorter for a maximum of 20 lumens per load.

2. **V-PRO maX sterilizer in:**

- Non-lumen cycles to sterilize non-lumened instruments including non-lumened rigid endoscopes and non-lumened hinged instruments, such as forceps or scissors.

- Lumen cycles to sterilize instruments with diffusion restricted areas, such as the hinged portion of forceps and scissors, and medical devices, including rigid endoscopes with a single stainless steel lumen with an inside diameter of 3mm or larger, and a length of 400mm or shorter for a maximum of 20 lumens per load.
- Flexible cycles to sterilize single or dual lumen surgical flexible endoscopes in either of two load configurations (per sterilizer manufacturer instruction):
    a. Two flexible endoscopes and no additional load, each having either:
        - a single lumen with an inside diameter of 1mm or larger, and a length of 1050mm or shorter, or
        - two lumens, with one having an inside diameter of 1mm or larger and a length of 998mm or shorter, and the second one an inside diameter of 1mm or larger and a length of 850mm or shorter.
    b. One flexible endoscope and load, each having either:
        - a single lumen with an inside diameter of 1mm or larger and a length of 1050mm or shorter, or
        - two lumens with one having an inside diameter of 1mm or larger and a length of 998mm or shorter and the second one an inside diameter of 1mm or larger and a length of 850mm or shorter.

The SteriTite Universal Container System is recommended to be used for the sterilization of surfaces and rigid or flexible lumens:

Table 1: SteriTite Universal Container System in AMSCO V-PRO sterilization.

Sterilizer	Cycle	Rigid lumens 3mm dia. or larger and 400 mm long or shorter	Flexible lumens 1mm dia. or larger and 1050mm long or shorter	Surfaces
Amsco V-PRO 1Plus	Lumen cycle	X		
	Non-lumen cycle			X
Amsco V-PRO Max	Lumen cycle	X		
	Non-lumen cycle			X
	Flexible cycle		X	

Note:

Lumen cycle parameters are the same for both sterilizer models referred to in the current submission.

Non-Lumen cycle parameters are the same for both sterilizer models referred to in the current submission.

Table 2 below identifies the SteriTite Universal Sealed Containers with disposable filters, which may be sterilized in Amsco V-PRO 1 Plus, and Amsco V-PRO Max low temperature Sterilization System:

Part Number	Description	Amsco V-PRO 1 Plus w/ polypropylene disposable filter	Amsco V-PRO maX w/ polypropylene disposable filter	Maximum load (lbs) inclusive of sealed container weight
SC02MG	2" high Endo mini-size w/ perforated base	X	X	5.63
SC03MG	3" high Endo mini-size w/ perforated base	X	X	5.63
SC02NG	2" high Endo mid-size w/ perforated base	X	X	8.85
SC03NG	3" high Endo mid-size w/ perforated base	X	X	8.85
SC04HG	4" high Half-size w/ perforated base	X	X	9.90
SC06HG	6" high Half-size w/ perforated base	X	X	12.05
SC08HG	8" high Half-size w/ perforated base	X	X	15.92
SC04QG	4" high Mid-size w/ perforated base	X	X	15.70
SC06QG	6" high Mid-size w/ perforated base	X	X	16.35
SC08QG	8" high Mid-size w/ perforated base	X	X	19.97
SC04FG	4" high Full-size w/ perforated base	X	X	19.97
SC06FG	6" high Full-size w/ perforated base	X	X	19.97
SC08FG	8" high Full-size w/ perforated base	X	X	19.97
SC05WG	5" high Extra Wide w/ perforated base	X	X	19.97

Note: All containers for Amsco V-PRO 1 Plus and V-PRO maX low temperature Sterilization System are perforated bottom containers, which must be used with single-use non-woven Polypro filter.

Table 3. MediTray Products Compatibility Table

MEDITRAY PRODUCT	Amsco V-PRO 1 Plus	Amsco V-PRO maX
Baskets	X	X
Trays	X	X
Insert Boxes	X	X
Metal Brackets	X	X
Metal Partitions	X	X
Posts	X	X
Silicone Brackets	X	X
Racks	X	X
Stringers	X	X

Table 4. SteriTite Accessories Compatibility

SteriTite Accessories	Amsco V-PRO 1 Plus	Amsco V-PRO maX
SCF02 Round filter	X	X
SCFM02 Rectangular filter	X	X
SCS01W Tamper Evident Seals	X	X
SCLH2O23 Load Card Large	X	X
SCLH2O24 Load Card Small	X	X

Internal Stacking:

In Steris V-PRO 1 Plus, and V-PRO maX Non Lumen and Flexible Cycles, up to two (2) layers of baskets with insert box or four (4) layers of trays with insert box may be stacked within the SteriTite Universal Container System.

MediTray case/trays and insert boxes with lid and base are designed to contain items and are not meant to be stacked one on top of the other.

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

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

Elizabeth F. Jarvis-Wells

(Division Sign-Off) Concurrence of CDRH, Office of Device Evaluation (ODE)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K112904