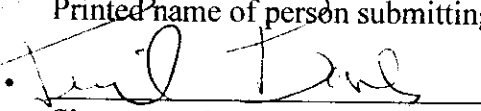


**510(k) Summary of  
Safety and Effectiveness**

MAR 13 2006

K052567

Submitter: Sterile Containment Technology, LLC  
1301 Quarry Court  
Suit 204  
Point Richmond, CA 94801  
510-412-6383 (phone)  
510-588-4699 (fax)

- Establishment FDA Registration No.: 3003793526
- Date Summary was prepared August 30<sup>th</sup>, 2005
- Percival Banks  
Printed name of person submitting for 510(k)
-   
Signature of person submitting for 510(k)
- President  
Title of person submitting for 510(k)

**Device Name and Classification**

**Trade Name:** ONE TRAY<sup>®</sup> Sealed Sterilization Container  
**Classification Name:** Sterilization Wrap  
**Common Name:** Sterilization, Rigid Reusable Case  
**Device Classification:** General Hospital, Class II, Regulation No. 880.6850  
**Product Code:** 80FRG

**Predicate Device**

Case Medical SteriTite<sup>®</sup> K960738 and K022978

**Additional Predicate Devices**

Medin K833343 and FlashPak K871202

**Device Description**

ONE TRAY<sup>®</sup> is a sealed rigid container with a rectangular patterned group of perforations forming vented areas in the lid and base. Disposable hydrophobic SMS filters cover each vented area and are held firmly in place by a perforated stainless steel filter cover. This assembly permits the penetration of steam during the sterilization process and serves as a bacterial and fluid barrier at the conclusion of the sterilization cycle.

## **Intended Use**

The ONE TRAY<sup>®</sup> Sealed Sterilization Containers are intended to be used for rapid sterilization of instruments or instrument sets in flash cycles. The containers are intended to be used to hold medical devices during steam sterilization. The complete line of ONE TRAY<sup>®</sup> Sealed Sterilization Containers can be processed in both flash steam pre-vacuum and gravity cycles.

After sterilization, ONE TRAY<sup>®</sup> provides for the safe transport and assured delivery of the enclosed devices in a sealed container with tamper evident protection according to AAMI and AORN guidelines.

## **Technical Characteristics**

The ONE TRAY<sup>®</sup> design is rectangular in shape and has vents in the lid and floor. The ONE TRAY<sup>®</sup> design/performance concept takes advantage of the thermodynamic behavior of steam to facilitate the expeditious and complete introduction of the sterilant throughout the container. This is accomplished by incorporating a specific number of proportionate size vents in strategic locations in both the lid and base. As the sterilizing media (steam) fills up the chamber of the sterilizer, it is introduced into the container through the dedicated entry vent in the lid of ONE TRAY<sup>®</sup>. This dedicated entry port provides for displacement of the atmosphere within the container from the top to the bottom.

The vents located in the extreme lateral portions of the floor provide two dedicated exit ports that offer twice the vapor exchange capacity of the single entry vent in the lid. This relationship facilitates the complete, consistent and expeditious displacement of the atmosphere by the sterilant throughout the ONE TRAY<sup>®</sup> container.

## **Performance Testing**

Testing was performed in order to determine the functional equivalency between the ONE TRAY<sup>®</sup> and the predicate device. Performance testing of the ONE TRAY<sup>®</sup> included, steam penetration, half cycle validation, package integrity, shelf life, material compatibility and biocompatibility studies. Based on the results of laboratory tests; the ONE TRAY<sup>®</sup> is substantially equivalent to the predicate container.

## **Conclusion**

Supportive data has demonstrated that the ONE TRAY<sup>®</sup> is substantially equivalent to the predicate device in that they have the same intended uses and the performance attributes are the same. The use of the ONE TRAY<sup>®</sup> raises no issues related to its safety or effectiveness and therefore the ONE TRAY<sup>®</sup> should be allowed for market in the United States.



MAR 13 2006

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

Mr. Gage Garman  
Sterile Containment Technology, Limited Liability Company  
1301 Quarry Court, Suite 204  
Point Richmond, California 94801

Re: K052567  
Trade/Device Name: ONE TRAY® Sealed Sterilization Container  
Regulation Number: 21 CFR 880.6850  
Regulation Name: Sterilization Wrap  
Regulatory Class: II  
Product Code: KCT  
Dated: February 11, 2006  
Received: February 16, 2006

Dear Mr. Garman:

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.

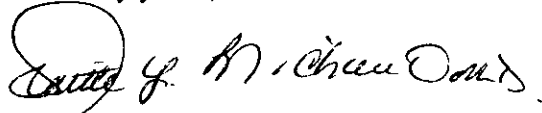
Page 2 – Mr. Gage Garman

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,



Chiu Lin, Ph.D.

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: K052567

Device Name: ONE TRAY® Sealed Sterilization Container

Indications For Use:

ONE TRAY® Sealed Sterilization Containers are intended to be used to hold temperature tolerant medical devices, surgical supplies, single instruments, multiple instruments or an instrument set for immediate use following flash sterilization. This includes sterilization of lumens 3 mm in diameter or larger with lengths of up to 400 mm.

ONE TRAY® Sealed Sterilization Containers are available in the following sizes:

<b>ONE TRAY System Components</b>		
<b>Product No.</b>	<b>Product Name</b>	<b>Description</b>
<b>ONE 20 Model</b>		
OTS-MB2000	ONE 20ML Base	ONE 20ML Base - 20" Low Profile Base (Metal, Blue, 11.5"x20.5"x3")
OTS-MB2001	ONE 20MH Base	ONE 20MH Base - 20" High Profile Base (Metal, Blue, 11.5"x20.5"x5")
OTS-MB2010	ONE 20ML Cover	ONE 20ML Cover - 20" Low Profile Cover (Metal, Blue, 11.5"x20.5"x1")
OTS-MB2011	ONE 20MH Cover	ONE 20MH Cover - 20" High Profile Cover (Metal, Blue, 11.5"x20.5"x2.5")
OTS-MB2020	ONE 20M Deck	ONE 20M Deck -20" Deck Plate (Metal, Blue, 11.5"x20.5")
<b>ONE 23 Model</b>		
OTS-MB2300	ONE 23ML Base	ONE 23ML Base - 23" Low Profile Base (Metal, Blue, 11.5"x23.5"x3")
OTS-MB2301	ONE 23MH Base	ONE 23MH Base - 23" High Profile Base (Metal, Blue, 11.5"x23.5"x5")
OTS-MB2310	ONE 23ML Cover	ONE 23ML Cover - 23" Low Profile Cover (Metal, Blue, 11.5"x23.5"x1")
OTS-MB2311	ONE 23MH Cover	ONE 23MH Cover - 23" High Profile Cover (Metal, Blue, 11.5"x23.5"x2.5")
OTS-MB2320	ONE 23M Deck	ONE 23M Deck -23" Deck Plate (Metal, Blue, 11.5"x23.5")

The ONE TRAY® components listed in the preceding table have been validated in all of the various size configurations listed in the following table to process a twenty five pound (25 lb) gross weight load (single container plus contents) in a steam pre-vacuum cycle at 132°C for 4 minutes exposure time; or in a steam gravity cycle at 132°C for 34 minutes exposure time.

*Shelby A. M... 3/4/06*  
 Page 1 of 2  
 ... General Hospital  
 ...  
 - K052567

ONE 20 Model			ONE 23 Model		
Name	Description	Product No.	Name	Description	Product No.
ONE 20MH	③ High Profile Base	OTS-MB2001	ONE 23MH	③ High Profile Base	OTS-MB2301
	③ High Profile Cover	OTS-MB2011		③ High Profile Cover	OTS-MB2311
	③ Deck Plate	OTS-MB2020		③ Deck Plate	OTS-MB2320
ONE 20MHL	③ High Profile Base	OTS-MB2001	ONE 23MHL	③ High Profile Base	OTS-MB2301
	③ Low Cover	OTS-MB2010		③ Low Cover	OTS-MB2310
	③ Deck Plate	OTS-MB2020		③ Deck Plate	OTS-MB2320
ONE 20MLH	③ Low Profile Base	OTS-MB2000	ONE 23MLH	③ Low Profile Base	OTS-MB2300
	③ High Profile Cover	OTS-MB2011		③ High Profile Cover	OTS-MB2311
	③ Deck Plate	OTS-MB2020		③ Deck Plate	OTS-MB2320
ONE 20ML	③ Low Profile Base	OTS-MB2000	ONE 23ML	③ Low Profile Base	OTS-MB2300
	③ Low Profile Cover	OTS-MB2010		③ Low Profile Cover	OTS-MB2310
	③ Deck Plate	OTS-MB2020		③ Deck Plate	OTS-MB2320

After sterilization, ONE TRAY provides for the safe transport and assured delivery for immediate use of the enclosed devices in a sealed container with tamper evident security and load record documentation according to AAMI and AORN guidelines.

The performance and intended use of ONE TRAY Sealed Sterilization Containers should comply at all times with the methods of use and flash sterilization guidelines as recommended by the manufacturer of the devices being sterilized, AAMI (Association for the Advance of Medical Instrumentation), AORN (Association of periOperative Nurses), ASHCSP (American Society of Healthcare Central Service Professionals), NIHSPD (National Institute for the Certification of Healthcare Sterile Processing and Distribution Personnel) and IAHCSPM (International Association of Healthcare Central Service Materiel Management)

Prescription Use \_\_\_\_\_ AND/OR Over-The-Counter Use  X   
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Page 2 of 2

*Shirley A. Murphy* 3/9/04

Shirley A. Murphy, General Manager  
Office of Device Evaluation

K 052567