



Food and Drug Administration  
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October 20, 2015

PMBS, LLC  
c/o Ms. Annette Hillring  
President  
Hillring & Associates, Inc.  
3012 St. Charles Dr.  
Tampa, FL 33618

Re: K152014

Trade/Device Name: MTS300 Multiple Tray Sterilization System  
Regulation Number: 21 CFR 880.6850  
Regulation Name: Sterilization Wrap  
Regulatory Class: II  
Product Code: KCT  
Dated: September 16, 2015  
Received: September 17, 2015

Dear Ms. Hillring:

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 contact the Division of Industry and Consumer Education 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>. 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 Industry and Consumer Education 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,

*Tejashri Purohit-Sheth, M.D.*

Tejashri Purohit-Sheth, M.D.  
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Center for Devices and  
Radiological Health

Enclosure

## Indications for Use

510(k) Number (if known)

K152014

Device Name

MTS300 Multiple Tray Sterilization System

Indications for Use (Describe)

The MTS300 System is indicated for enclosing other medical devices that are to be sterilized by a healthcare provider. It is intended to allow sterilization of the enclosed materials and maintain sterility for up to 30 days until used. The unit must be used with the MTS300 Transfer Cart, MTS300 filters and integrity locks.

The MTS300 System is intended to be used in prevacuum steam sterilizers with a prevacuum cycle of 270°F and exposure time of 4 minutes. Use no more than 3 trays per shelf or 25 lbs. per tray.

The MTS300 System was tested and validated with rigid instruments containing lumens with an inner diameter of 3.8mm and an overall length of 370mm. Do not use with instruments containing lumens with an inner diameter smaller than 3.8mm and an overall length longer than 370mm.

Use only uncovered, perforated or wire mesh general delivery trays within the MTS300 System.

Type of Use (Select one or both, as applicable)

Prescription Use (Part 21 CFR 801 Subpart D)

Over-The-Counter Use (21 CFR 801 Subpart C)

### CONTINUE ON A SEPARATE PAGE IF NEEDED.

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## 510(k) Summary

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**Date Prepared** September 16, 2015

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**Submitter** Michele E. Mauzerall  
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**Device**

- Trade Name: MTS300 Multiple Tray Sterilization System
- Common Name: Sterilization Container and Accessories
- Classification Name: Sterilization Wrap Containers, Trays, Cassettes & Other Accessories
- Product Code: KCT
- Classification Regulation: 21 CFR 880.6850 Sterilization wrap, Class II

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**Predicate Device** AmMed Surgical Equipment, LLC, S.C.O.R.E.S. Units, Self Contained Operating Room Equipment Sterilization Containers cleared via Premarket Notification 510(k) K110898 on July 26, 2012

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**Device Description** The MTS300 Multiple Tray Sterilization System (also referred to as the MTS300 System) includes the stainless steel sterilization cabinet and adjustable transfer cart. Single use filters and integrity locks with sterilization indicator dots are used with the system for each sterilization cycle. An optional STEAMPlus™ tray record card with STEAMPlus sterilization integrator (SPS Medical) may be utilized by the healthcare provider. The MTS System is intended to sterilize a maximum weight of 300 pounds of devices and instruments for a single patient surgery. The loaded cabinet is deployed from the adjustable transfer cart and processed in a pre-vacuum steam sterilizer and then dried for 30 minutes. Sterility is maintained for up to 30 days.

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**Indications for Use** The MTS300 System is indicated for enclosing other medical devices that are to be sterilized by a healthcare provider. It is intended to allow sterilization of the enclosed materials and maintain sterility for up to 30 days until used. The

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## 510(k) Summary, Continued

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**Indications for Use, continued**

unit must be used with the MTS300 Transfer Cart, MTS300 filters and integrity locks.

The MTS300 System is intended to be used in prevacuum steam sterilizers with a prevacuum cycle of 270°F and exposure time of 4 minutes. Use no more than 3 trays per shelf or 25 lbs. per tray.

The MTS300 System was tested and validated with rigid instruments containing lumens with an inner diameter of 3.8mm and an overall length of 370mm. Do not use with instruments containing lumens with an inner diameter smaller than 3.8mm and an overall length longer than 370mm.

Use only uncovered, perforated or wire mesh general delivery trays within the MTS300 System.

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**Comparison of Technological Characteristics with the Predicate Device**

There are no new technological characteristics associated with the MTS300 Multiple Tray Sterilization System as compared to the predicate device, the S.C.O.R.E.S. Units, Self Contained Operating Room Equipment Sterilization Container. A comparison of the technological characteristics of the subject device, the MTS300 Multiple Tray Sterilization System, to the predicate device, the S.C.O.R.E.S. Units, Self Contained Operating Room Equipment Sterilization Container is provided in the table on the following page.

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## 510(k) Summary, Continued

### Comparison of Technological Characteristics with the Predicate Device, continued

Characteristic	Subject Device: <b>MTS300 Multiple Tray Sterilization System (“MTS300 System”) K152015</b>	Predicate Device: <b>S.C.O.R.E.S. Units, Self Contained Operating Room Equipment Sterilization Container K110898</b>
Indications for Use	<p>The MTS300 System is indicated for enclosing other medical devices that are to be sterilized by a healthcare provider. It is intended to allow sterilization of the enclosed materials and maintain sterility for up to 30 days until used. The unit must be used with the MTS300 Transfer Cart, MTS300 filters and integrity locks.</p> <p>The MTS300 System is intended to be used in prevacuum steam sterilizers with a prevacuum cycle of 270°F and exposure time of 4 minutes. Use no more than 3 trays per shelf or 25 lbs. per tray.</p> <p>The MTS300 System was tested and validated with rigid instruments containing lumens with an inner diameter of 3.8mm and an overall length of 370mm. Do not use with instruments containing lumens with an inner diameter smaller than 3.8mm and an overall length longer than 370mm.</p> <p>Use only uncovered, perforated or wire mesh general delivery trays within the MTS300 System.</p>	<p>The SCORES Sterilization Container is indicated for enclosing other medical devices that are to be sterilized by a healthcare provider. It is intended to allow sterilization of the enclosed materials and maintain sterility for up to 30 days until used. The unit must be used with the SCORES Transfer Cart, SCORES filters and integrity locks.</p> <p>The unit is intended to be used in prevacuum steam sterilizers with a prevacuum cycle of 270°F and exposure time of 4 minutes. Use no more than 3 trays per shelf or 25 lbs. per tray.</p> <p>The SCORES Unit was tested and validated with rigid instruments containing lumens with an inner diameter of 3.8mm and an overall length of 370mm. Do not use with instruments containing lumens with an inner diameter smaller than 3.8mm and an overall length longer than 370mm.</p> <p>Use only uncovered, perforated or wire mesh general delivery trays within the SCORES Sterilization Container.</p>

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## 510(k) Summary, Continued

### Comparison of Technological Characteristics with the Predicate Device, continued

Characteristic	Subject Device: MTS300 Multiple Tray Sterilization System (“MTS300 System”) K152015	Predicate Device: S.C.O.R.E.S. Units, Self Contained Operating Room Equipment Sterilization Container K110898
Sterilization Parameters	Prevacuum cycle of 270°F and exposure time of 4 minutes	Prevacuum cycle of 270°F and exposure time of 4 minutes
Drying Time	30 minutes	30 minutes
Sterility Maintenance	30 days	30 days
Cabinet Material	16 gauge stainless steel	12 and 14 gauge stainless steel
Weight w/ Shelves	212 lbs.	214 lbs.
Filter Material	Heavy duty sterilization wrap by SPS Medical	Heavy duty sterilization wrap by SPS Medical
Volume-to-Vent Ratio	129.131	192.22
Deployment into Sterilization Chamber	Adjustable transfer cart	Adjustable transfer cart
Recommended Sterilization Trays	All manufacturers’ trays - uncovered, perforated or wire mesh general delivery trays	All manufacturers’ trays - uncovered, perforated or wire mesh general delivery trays
Recommended Sterilizers	All makes and models with dimensions compatible with the MTS System	Three Steris models

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## 510(k) Summary, Continued

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**Comparison of Technological Characteristics with the Predicate Device,**  
continued

Modifications introduced into the MTS300 Multiple Tray Sterilization System do not affect the technological characteristics. The cabinet material remains stainless steel and a filtration system utilizing disposable filters of the same material from the same supplier (with only dimensional changes) is the method by which sterilization is achieved and maintained. The cabinet continues to be deployed into the sterilization chamber with an adjustable transfer cart. The sterilization parameters, drying time and sterility maintenance specifications are identical to the predicate device along with the indications for use.

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**Performance Data**

Nonclinical data was generated to ensure the MTS300 Multiple Tray Sterilization System continues to meet the intended use. Sterilization efficacy verification studies were performed in accordance with the requirements of ANSI/AAMI ST77:2013 *Containment devices for reusable medical device sterilization* and the recommendations of *Premarket Notification [510(k)] Submissions for Medical Sterilization Packaging Systems in Healthcare Facilities, Draft Guidance for Industry and FDA*, March 7, 2002, and included all of the studies performed on the predicate device. Stability of the system (cabinet on transfer cart) was demonstrated by an engineering analysis and within a usability study. The usability study demonstrated that the modified cabinet and adjustable transfer cart will continue to meet user needs and intended use.

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**Conclusions**

In accordance with the Federal Food, Drug and Cosmetic Act and 21 CFR 807, and based upon the information and scientifically valid data provided in this premarket notification, PMBS, LLC, concludes that the subject device, the MTS300 Multiple Tray Sterilization System is as safe, as effective and performs as well as the predicate device, the S.C.O.R.E.S. Units, Self Contained Operating Room Equipment Sterilization Container (K110898).

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