DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

July 13, 2017

Aesculap, Inc
Paul Amudala
Regulatory Affairs Specialist
3773 Corporate Pkwy
Center Valley, Pennsylvania 18034

Re: K162815
Trade/Device Name: SterilContainer™ S System
Regulation Number: 21 CFR 880.6850
Regulation Name: Sterilization Wrap
Regulatory Class: Class II
Product Code: KCT
Dated: June 9, 2017
Received: June 12, 2017

Dear Paul Amudala:

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" (21 CFR 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,

Tara A. Ryan -S

for

Lori Wiggins
Acting Director
Division of Anesthesiology,
General Hospital, Respiratory,
Infection Control, and Dental Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

# Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
*See PRA Statement below.*

510(k) Number *(if known)*

K162815

Device Name
SterilContainer™ S System

Indications for Use *(Describe)*

The SterilContainer S System is a reusable sterilization container system (consisting of perforated bottoms and perforated lids with filter retention plates, and single use polypropylene filters) intended to be used to enclose another medical device that is to be sterilized by a healthcare provider. This container system has been validated with stainless steel and Teflon lumens, hinged, and knurled instruments. It is intended to allow sterilization of the enclosed device and also maintain sterility of the enclosed device until used. This container system is compatible for use with the TS03 Sterizone VP4 Low Temperature Sterilization System. The SterilContainer S System includes accessories such as silicone mats, baskets, trays, racks, eyepiece holders and sleeve holders.

**Table 1: Validated TS03 Sterilizer Flexible Cycle Load Configurations**

| | |
|---|---|
| **Load #1 (31.2 lb)** | Flexible endoscopes load accommodating three single channel flexible endoscopes, one per container:<br>• Internal channel diameter of 1 mm and length of 850 mm. |
| **Load #2 (29.4 lb)** | Semi-rigid and rigid channel devices load accommodating three double channel semi-rigid endoscopes, one per container, and one length of medical grade stainless steel tubing.<br>• Length of tubing:<br>➢ Internal channel diameter of 1.0 mm and length of 500 mm.<br>• Double channel semi-rigid endoscope<br>➢ Internal channel diameters of 0.7 mm and 1.1 mm, and length of 500 mm |
| **Load #3 (10.2 lb)** | Worst-case volume to surface perforation area ratio using a perforated container including two stacked baskets. Each basket was covered with a full length silicone mat. At least one inoculated medical device was added per level of the container. |
| **Load #4 (25 lb)** | Worst-case volume to surface perforation area ratio using a perforated container with maximum weight of instrument, for a total mass of 25 lb. At least three inoculated medical devices were added in the container. |
| **Load #5 (75 lb)** | Heavy weight load composed of three perforated containers, with a total mass of 25 lb per container. The heavy validation load was prepared based on the Aesculap® SterilContainer™ S container lethality studies (PRO-169) and adapted to include a maximum weight in a single load. |

**Table 2: TS03 -Sterilizer Flexible Cycle Compatible SterilContainer *S* Container Systems**

| Lid | Bottom | Description | Total Loaded Container Weight (if container does not contain a flexible endoscope or bronchoscope)* |
|---|---|---|---|

| | | | |
|---|---|---|---|
| JM489 | JM440 | Full Size 90mm (4 ¼") | **25 lbs** for one container in the chamber |
| | JM441 | Full Size 120mm (5 ½") | |
| | JM442 | Full Size 135mm (6") | |
| | JM444 | Full Size 187mm (8") | |
| JM789 | JM740 | ¾ Size 90mm(4 ¼") | |
| | JM741 | ¾ Size 120mm (5 ½") | |
| | JM742 | ¾ Size 135mm (6") | |
| JM389 | JM340 | ½ Size 90mm (4 ¼") | |
| | JM341 | ½ Size 120mm (5 ½") | |
| | JM342 | ½ Size 135mm (6") | |

*Loads containing a flexible endoscope or bronchoscope should follow Table 1 recommendations

**Table 3: TS03 Sterilizer Cycle Compatible Accessories**

| Accessories | TS03 Cycle |
|---|---|
| Stainless Steel baskets, basket lids, and dividers | Yes |
| Instrument Organization System (Silicone and Stainless Steel racks, brackets, holders, and clamps) | Yes |
| Silicone mats | Yes |
| Stainless Steel racks, trays, holders, clamps, brackets, and platforms | Yes |

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 (as required by 21 CFR 807.92)

SterilContainer™ *S* System

July 7, 2017

**COMPANY:** Aesculap®, Inc.
3773 Corporate Parkway
Center Valley, PA 18034
Establishment Registration Number: 2916714

**CONTACT:** Paul Amudala
610-984-9303 (phone)
610-791-6882 (fax)

**TRADE NAME:** SterilContainer *S* System

**COMMON NAME**: Sterilization Container Wrap

**CLASSIFICATION NAME:** Sterilization Wrap

**REGULATION NUMBER:** 880.6850

**PRODUCT CODE:** KCT

**DEVICE CLASS:** Class II per 21 CFR §880.6850

## SUBSTANTIAL EQUIVALENCE

Aesculap®, Inc. believes that the SterilContainer™ *S* System for use in TS03 Sterizone VP4 Low Temperature Sterilization System is substantially equivalent to Aesculap SterilContainer™ *S* for use in V-Pro 60 Flexible Cycle via K151242.

## DEVICE DESCRIPTION

The SterilContainer™ *S* System is a container system that will allow for sterilization and storage of medical devices. This container system can be used in the TS03 Sterizone VP4 Low Temperature Sterilization System. The SterilContainer™ *S* System rigid containers are made from non-anodized Aluminum and utilize disposable (single use) polypropylene filters. The SterilContainer™ *S* System includes accessories such as mats, baskets, trays, holders, organizers, filters, indicator cards and tamper proof locks.

### Indications for Use:

The SterilContainer *S* System is a reusable sterilization container system (consisting of perforated bottoms and perforated lids with filter retention plates, and single use polypropylene filters) intended to be used to enclose another medical device that is to be sterilized by a healthcare provider. This container system has been validated with stainless steel and Teflon

lumens, hinged, and knurled instruments. It is intended to allow sterilization of the enclosed device and also maintain sterility of the enclosed device until used. This container system is compatible for use with the TS03 Sterizone VP4 Low Temperature Sterilization System. The SterilContainer *S* System includes accessories such as silicone mats, baskets, trays, racks, eyepiece holders and sleeve holders.

**Table 1: Validated TS03 Sterizone VP4 Cycle Load Configurations**

| | |
|---|---|
| **Load #1 (31.2 lb)** | Flexible endoscopes load accommodating three single channel flexible endoscopes, one per container:<br>• Internal channel diameter of 1 mm and length of 850 mm. |
| **Load #2 (29.4 lb)** | Semi-rigid and rigid channel devices load accommodating three double channel semi-rigid endoscopes, one per container, and one length of medical grade stainless steel tubing.<br>• Length of tubing:<br>➢ Internal channel diameter of 1.0 mm and length of 500 mm.<br>• Double channel semi-rigid endoscope<br>➢ Internal channel diameters of 0.7 mm and 1.1 mm, and length of 500 mm |
| **Load #3 (10.2 lb)** | Worst-case volume to surface perforation area ratio using a perforated container including two stacked baskets. Each basket was covered with a full length silicone mat. At least one inoculated medical device was added per level of the container. |
| **Load #4 (25 lb)** | Worst-case volume to surface perforation area ratio using a perforated container with maximum weight of instrument, for a total mass of 25 lb. At least three inoculated medical devices were added in the container. |
| **Load #5 (75 lb)** | Heavy weight load composed of three perforated containers, with a total mass of 25 lb per container. The heavy validation load was prepared based on the Aesculap® SterilContainer™ S container lethality studies (PRO-169) and adapted to include a maximum weight in a single load. |

**Table 2: TS03 Sterilizer Cycle Compatible SterilContainer *S* Container Systems**

| Lid | Bottom | Description | Total Loaded Container Weight (if container does not contain a flexible endoscope or bronchoscope)* |
|---|---|---|---|
| JM489 | JM440 | Full Size 90mm (4 ¼”) | **25 lbs** for one container in the chamber |
| | JM441 | Full Size 120mm (5 ½”) | |
| | JM442 | Full Size 135mm (6”) | |
| | JM444 | Full Size 187mm (8”) | |
| JM789 | JM740 | ¾ Size 90mm(4 ¼”) | |
| | JM741 | ¾ Size 120mm (5 ½”) | |
| | JM742 | ¾ Size 135mm (6”) | |

| | | | |
|---|---|---|---|
| JM389 | JM340 | ½ Size 90mm (4 ¼") | |
| | JM341 | ½ Size 120mm (5 ½") | |
| | JM342 | ½ Size 135mm (6") | |

*Loads containing a flexible endoscope or bronchoscope should follow Table 1 recommendations

**Table 3: TS03 Sterilizer Cycle Compatible Accessories**

| Accessories | TS03 Cycle |
|---|---|
| Stainless Steel baskets, basket lids, and dividers | Yes |
| Instrument Organization System (Silicone and Stainless Steel racks, brackets, holders, and clamps) | Yes |
| Silicone mats | Yes |
| Stainless Steel racks, trays, holders, clamps, brackets, and platforms | Yes |

## TECHNOLIGICAL CHARACTERISTICS (compared to predicate)

The SterilContainer *S* System that can be used in the TS03 Sterizone VP4 Low Sterilization cycle is the same container system that was cleared in K151242. The materials and design have not changed.

| System | SterilContainer *S* System (not assigned) | SterilContainer *S* System (K151242) |
|---|---|---|
| Sterilization process | TS03 Sterizone VP4 Low Temperature Sterilization System 46 min cycle, Ozone ($O_3$), $H_2O_2$ | V-PRO 60 38 min Low Temperature Flexible Cycle, $H_2O_2$ |
| Material | Non-anodized aluminum | Non-anodized aluminum |
| Container type | Perforated | Perforated |
| Filter type | Polypropylene | Polypropylene |

## PERFORMANCE DATA

The Aesculap SterilContainer *S* System has been validated for the TS03 Sterizone VP4 Low Temperature Sterilization System. These validations were conducted by a qualified testing laboratory. The performance testing demonstrates substantial equivalence to the predicate devices. The following performance testing has been completed to ensure substantial equivalence.

| Performance Properties | Results |
|---|---|
| Sterilization Efficacy/ Lethality Study | Testing demonstrated a 12 log reduction and a sterility assurance level (SAL) of $10^{-6}$ using the biological (BI) overkill method and half-cycle validation. The SAL was achieved by placing at least 1.0 x $10^6$ spores of Geobacillus stearothermophilus in the worst-case sterilization location through the containers and processing at one-half the expected full cycle exposure time. Following exposure, the Bi's were aseptically transferred to culture media and incubated as required. This testing was performed in triplicate on the Aesculap rigid container. The full cycle therefore results in a 12-log reduction of spores and produce a $10^{-6}$ SAL, which reflects a one-in-a-million chance of non-sterile item. |
| Bacterial Filtration Efficiency | The evaluation of the microbial barrier properties of the Aesculap® polypropylene filters demonstrates that the bacterial filtration efficiency is maintained by the filter after being processed in the Cycle 1 of the STERIZONE® Sterilizer. |
| Event Related Sterility Maintenance | Testing demonstrated the ability to provide an effective barrier for maintaining sterility of the contents after processing followed by a 180 day event related storage under conditions which simulate hospital sterile package handling and storage conditions. |
| Material Compatibility/Reuse Test | After 100 cycles of processing no visible or functional changes were observed |
| Biocompatibility | This study is conducted to evaluate the biocompatibility properties of the Aesculap® polypropylene filters when processed in Cycle 1 of the STERIZONE® VP4 Sterilizer. The Aesculap® polypropylene filters have been proven to be biocompatible and can be safely processed in Cycle 1 of the STERIZONE® Sterilizer. |
| Aerosol Microbial Challenge | The contents of container were negative for growth following exposure of the containers to aerosolized microbial challenge test conditions |

**Conclusion**:

The Aesculap SterilContainer *S* System is substantially equivalent to the predicate device.