July 5, 2019

Aesculap, Inc.
Sierra Mertz
Regulatory Affairs Specialist
3773 Corporate Parkway
Center Valley, Pennsylvania 18034

Re: K182414
Trade/Device Name: Aesculap® SterilContainer™ S2 System
Regulation Number: 21 CFR 880.6850
Regulation Name: Sterilization Wrap
Regulatory Class: Class II
Product Code: KCT
Dated: June 6, 2019
Received: June 7, 2019

Dear Sierra Mertz:

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

For Elizabeth Claverie, M.S.
Assistant Director for THT4B2
Acting Assistant Director for THT4B1
DHT4B: Division of Infection Control
and Plastic Surgery Devices
OHT4: Office of Surgical
and Infection Control Devices
Office of Product Evaluation and Quality
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)*
K182414

Device Name
Aesculap(R) SterilContainer™ S2 System

Indications for Use *(Describe)*
The Aesculap(R) SterilContainer™ S2 System is a reusable rigid sterilization container system intended to be used to enclose another medical device that is to be sterilized by a healthcare provider. 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 in the following sterilization modalities:

- Dynamic-air removal steam (PreVac) (Exposure: 270°F for 4 minutes with 15 minute dry time)
- Gravity Steam (Exposure: 250°F for 30-60 minutes with 15 minute dry time)
- STERRAD 100S, STERRAD NX Standard, STERRAD NX Advanced, STERRAD 100NX Standard, STERRAD 100NX Flex Cycles
- STERIS V-PRO 60 Lumen, V-PRO 60 Non-Lumen, V-PRO 60 Flex, V-PRO maX Lumen, V-PRO maX Non-Lumen, and V-PRO maX Flex Cycles.

The Aesculap SterilContainer S2 System includes accessories such as silicone mats and organizers, stainless steel baskets, trays, holders, sterilization indicator cards and tamper proof locks.

The attached table identifies the validated load configurations for each of the modalities.

Table 1. SterilContainer S2 System Validated Load Configurations

Sterilization Cycle	Container Size	Validated Load Configuration
Dynamic Air Removal Steam (PreVac)	Full	1 lumen with ≥ 3mm ID x ≤400mm L and a second lumen ≥ 3.8mm ID x ≤370mm L
	Three-Quarter	
	Half	
Gravity Steam	Full	Non lumen stainless steel instruments
	Three-Quarter	
	Half	
STERRAD 100S	Full	5 Stainless steel lumens ≥ 3.0mm ID and ≤400mm L
	Three-Quarter	
	Half	
STERRAD NX Standard	Full	5 Stainless steel lumens ≥ 2mm ID and ≤400mm L
	Three-Quarter	
	Half	
STERRAD NX Advanced	Full	1 Flexible lumen (≥ 1mm ID and ≤850mm L)
	Three-Quarter	
	Half	
STERRAD 100NX Standard	Full	5 Stainless steel lumens ≥ 0.7mm ID and ≤ 500mm L
	Three-Quarter	
	Half	
STERRAD 100NX Flex	Full	1 Flexible Lumen 1mm ID and ≤850mm L
	Three-Quarter	
	Half	

STERIS V-PRO 60 Lumen	Full Three-Quarter Half	Stainless steel lumens 1 lumen ≥ 0.77mm ID and ≤410mm L 1 lumen ≥ 1.2mm ID and ≤275mm L 1 lumen ≥ 1.8mm ID and ≤310mm L 1 lumen ≥ 2.8mm ID and ≤317mm L
STERIS V-PRO 60 Non-Lumen	Full Three-Quarter Half	Non lumen stainless steel instruments
STERIS V-PRO 60 Flex	Full Three-Quarter Half	1 flexible surgical endoscope or bronchoscope with a light cord (if not integral to endoscope) and mat without any additional load. The flexible endoscope may be a single or dual lumens that are >1mm ID and <990 mm L
STERIS V-PRO maX Lumen	Full Three-Quarter Half	Stainless steel lumens 1 lumen ≥ 0.77mm ID and ≤527mm L 1 lumen ≥ 1.2mm ID and ≤275mm L 1 lumen ≥ 1.8mm ID and ≤310mm L 1 lumen ≥ 2.8mm ID and ≤317mm L 1 lumen ≥ 3.0mm ID and ≤400mm L
STERIS V-PRO maX Non-Lumen	Full Three-Quarter Half	Non lumen stainless steel instruments
STERIS V-PRO maX Flex	Full Three-Quarter Half	2 flexible endoscopes with a light cord (if not integral to endoscope) and mat with no additional load. The scopes can have: a single lumen that is ≥ 1 mm ID and ≤ 1050 mm L or two lumens with one ≥ 1 mm ID and ≤ 990 mm L and the other ≥ 1 mm ID and ≤ 850 mm L OR 1 flexible endoscope with a light cord (if not integral to endoscope) and mat and additional non-lumened instruments. The scope can have: a single lumen that is ≥ 1 mm ID and ≤ 1050 mm L or two lumens with one ≥ 1 mm ID and ≤ 990 mm L and the other ≥ 1 mm ID and ≤ 850 mm L

Table 2. SterilContainer S2 System Configurations – Prevac Steam and Gravity Steam

Sterilization Method	Container Size	Container Bottom Part #	Container Lid Part #	Total Loaded Container Weight*
Dynamic-air removal steam (PreVac) & Gravity Steam	Full Size - 4 ¼"	JS440	JS489	25 pounds
	Full Size - 5 ½"	JS441		
	Full Size - 6"	JS442		
	Full Size - 8"	JS444		
	Three-Quarter Size - 4 ¼ "	JS740	JS789	25 pounds
	Three-Quarter Size - 5 ½"	JS741		
	Three-Quarter Size - 6"	JS742		
	Half Size - 4 ¼ "	JS340	JS389	25 pounds
	Half Size - 5 ½	JS341		
	Half Size - 6"	JS342		

*Maximum load weight is 25 pounds or the maximum indicated weight for the sterilizer, whichever is less.

Table 3. Sterilization Cycle Compatible Accessories - Prevac Steam and Gravity Steam

Accessories	Compatible with Prevac Steam	Compatible with Gravity Steam
Stainless Steel baskets, basket lids, and dividers	Yes	Yes
Instrument Organization System (Silicone and Stainless Steel racks, brackets, holders, and clamps)	Yes	Yes
Silicone mats	Yes	Yes

Table 4. SterilContainer S2 System Configurations – STERRAD Sterilization Systems

Sterilization Method	Container Size	Container Bottom Part #	Container Lid Part #	Total Loaded Container Weight
STERRAD 100 S	Full Size - 4 ¼"	JS440	JS489	13.95 pounds
	Full Size - 5 ½"	JS441		
	Full Size - 6"	JS442		
	Full Size - 8"	JS444		
	Three-Quarter Size - 4 ¼"	JS740	JS789	13.90 pounds
	Three-Quarter Size - 5 ½"	JS741		
	Three-Quarter Size - 6"	JS742		
	Half Size - 4 ½"	JS340	JS389	13.90 pounds
	Half Size - 5 ½	JS341		
	Half Size - 6"	JS342		
STERRAD NX Standard	Full Size - 4 ¼"	JS440	JS489	10.70 pounds
	Full Size - 5 ½"	JS441		
	Full Size - 6"	JS442		
	Full Size - 8"	JS444		
	Three-Quarter Size - 4 ¼"	JS740	JS789	10.70 pounds
	Three-Quarter Size - 5 ½"	JS741		
	Three-Quarter Size - 6"	JS742		
	Half Size - 4 ¼"	JS340	JS389	10.70 pounds
	Half Size - 5 ½	JS341		
	Half Size - 6"	JS342		
STERRAD NX Advanced	Full Size - 4 ¼"	JS440	JS489	10.70 pounds
	Full Size - 5 ½"	JS441		
	Full Size - 6"	JS442		
	Full Size - 8"	JS444		
	Three-Quarter Size - 4 ¼"	JS740	JS789	10.70 pounds
	Three-Quarter Size - 5 ½"	JS741		
	Three-Quarter Size - 6"	JS742		
	Half Size - 4 ¼"	JS340	JS389	10.70 pounds
	Half Size - 5 ½	JS341		
	Half Size - 6"	JS342		
STERRAD 100NX Standard	Full Size - 4 ¼"	JS440	JS489	21.45 pounds
	Full Size - 5 ½"	JS441		
	Full Size - 6"	JS442		
	Full Size - 8"	JS444		
	Three-Quarter Size - 4 ¼"	JS740	JS789	13.85 pounds
	Three-Quarter Size - 5 ½"	JS741		
	Three-Quarter Size - 6"	JS742		

	Half Size - 4 ¼"	JS340	JS389	13.85 pounds
	Half Size - 5 ½	JS341		
	Half Size - 6"	JS342		
STERRAD 100NX Flex	Full Size - 4 ¼"	JS440	JS489	10.95 pounds
	Full Size - 5 ½"	JS441		
	Full Size - 6"	JS442		
	Full Size - 8"	JS444		
	Three-Quarter Size - 4 ¼"	JS740	JS789	10.35 pounds
	Three-Quarter Size - 5 ½"	JS741		
	Three-Quarter Size - 6"	JS742		
	Half Size - 4 ¼"	JS340	JS389	10.35 pounds
	Half Size - 5 ½	JS341		
	Half Size - 6"	JS342		

Table 5. Sterilization Cycle Compatible Accessories – STERRAD Sterilization Systems

Accessories	Compatible with 100S	Compatible with NX Standard	Compatible with NX Advanced	Compatible with 100NX Standard	Compatible with 100NX Flex
Stainless Steel baskets, basket lids, and dividers	Yes	Yes	Yes	Yes	Yes
Instrument Organization System (Silicone and Stainless Steel racks, brackets, holders, and clamps)	Yes	Yes	Yes	Yes	Yes
Silicone mats	Yes	No	Yes	No	No

Table 6. SterilContainer S2 System Configurations – STERIS Sterilization Systems

Sterilization Method	Container Size	Container Bottom Part #	Container Lid Part #	Total Loaded Container Weight
STERIS V-PRO 60 Lumen	Full Size - 4 ¼"	JS440	JS489	11.1 pounds
	Full Size - 5 ½"	JS441		
	Full Size - 6"	JS442		
	Full Size - 8"	JS444		
	Three-Quarter Size - 4 ¼"	JS740	JS789	9.6 pounds
	Three-Quarter Size - 5 ½"	JS741		
	Three-Quarter Size - 6"	JS742		
	Half Size - 4 ¼"	JS340	JS389	9.6 pounds
	Half Size - 5 ½	JS341		
	Half Size - 6"	JS342		
STERIS V-PRO 60 Non-Lumen	Full Size - 4 ¼"	JS440	JS489	12.0 pounds
	Full Size - 5 ½"	JS441		
	Full Size - 6"	JS442		
	Full Size - 8"	JS444		

	Three-Quarter Size - 4 ¼”	JS740	JS789	12.0 pounds
	Three-Quarter Size - 5 ½”	JS741		
	Three-Quarter Size - 6”	JS742		
	Half Size - 4 ¼”	JS340	JS389	12.0 pounds
	Half Size - 5 ½	JS341		
	Half Size - 6”	JS342		
STERIS V-PRO 60 Flex	Full Size - 4 ¼”	JS440	JS489	1 flexible surgical endoscope or bronchoscope with a light cord (if not integral to endoscope) and mat without any additional load. The flexible endoscope may be a single or dual lumens that are >1mm ID and <990 mm L
	Full Size - 5 ½”	JS441		
	Full Size - 6”	JS442		
	Full Size - 8”	JS444		
	Three-Quarter Size - 4 ¼”	JS740	JS789	1 flexible surgical endoscope or bronchoscope with a light cord (if not integral to endoscope) and mat without any additional load. The flexible endoscope may be a single or dual lumens that are >1mm ID and <990 mm L
	Three-Quarter Size - 5 ½”	JS741		
	Three-Quarter Size - 6”	JS742		
	Half Size - 4 ¼”	JS340	JS389	1 flexible surgical endoscope or bronchoscope with a light cord (if not integral to endoscope) and mat without any additional load. The flexible endoscope may be a single or dual lumens that are >1mm ID and <990 mm L
	Half Size - 5 ½	JS341		
	Half Size - 6”	JS342		
STERIS V-PRO maX Lumen	Full Size - 4 ¼”	JS440	JS489	11.1 pounds
	Full Size - 5 ½”	JS441		
	Full Size - 6”	JS442		
	Full Size - 8”	JS444		
	Three-Quarter Size - 4 ¼”	JS740	JS789	9.6 pounds
	Three-Quarter Size - 5 ½”	JS741		
	Three-Quarter Size - 6”	JS742		
	Half Size - 4 ¼”	JS340	JS389	9.6 pounds
	Half Size - 5 ½	JS341		
	Half Size - 6”	JS342		
STERIS V-PRO maX Non-Lumen	Full Size - 4 ¼”	JS440	JS489	18.6 pounds
	Full Size - 5 ½”	JS441		
	Full Size - 6”	JS442		
	Full Size - 8”	JS444		
	Three-Quarter Size - 4 ¼”	JS740	JS789	18.6 pounds
	Three-Quarter Size - 5 ½”	JS741		
	Three-Quarter Size - 6”	JS742		

	Half Size - 4 ¼"	JS340	JS389	18.6 pounds
	Half Size - 5 ½	JS341		
	Half Size - 6"	JS342		
STERIS V-PRO maX Flex	Full Size - 4 ¼"	JS440	JS489	10.3 pounds
	Full Size - 5 ½"	JS441		
	Full Size - 6"	JS442		
	Full Size - 8"	JS444		
	Three-Quarter Size - 4 ¼"	JS740	JS789	10.0 pounds
	Three-Quarter Size - 5 ½"	JS741		
	Three-Quarter Size - 6"	JS742		
	Half Size - 4 ¼"	JS340	JS389	10.0 pounds
	Half Size - 5 ½	JS341		
	Half Size - 6"	JS342		

Table 7. Sterilization Cycle Compatible Accessories – STERIS Sterilization Systems

Accessories	Compatible with V-PRO 60 Lumen	Compatible with V-PRO 60 Non-Lumen	Compatible with V-PRO 60 Flex	Compatible with V-PRO maX Lumen	Compatible with V-PRO maX Non-Lumen	Compatible with V-PRO maX Flex
Stainless Steel baskets, basket lids, and dividers	Yes	*Yes*	Yes	Yes	Yes	Yes
Instrument Organization System (Silicone and Stainless Steel racks, brackets, holders, and clamps)	Yes	Yes	Yes	Yes	Yes	Yes
Silicone mats	No	No	No	No	No	No

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) SUMMARY (as required by 21 CFR 807.92)

Aesculap® SterilContainer™ S2 System
For Steam & Low Temperature Sterilization Cycles
July 5, 2019

COMPANY:	Aesculap, Inc. 3773 Corporate Parkway Center Valley, PA 18034 Establishment Registration Number: 2916714
CONTACT:	Sierra M. Mertz 610-984-9076 (phone) Sierra.Mertz@aesculapimplants.com 610-791-6882 (fax)
TRADE NAME:	Aesculap® SterilContainer™ S2 System
COMMON NAME:	Sterilization Container Wrap
CLASSIFICATION NAME:	Wrap, Sterilization
REGULATION NUMBER:	880.6850
PRODUCT CODE:	KCT
DEVICE CLASS:	Class II

Predicate Device
Aesculap SterilContainer System (K792558)

Reference Device
Aesculap SterilContainer S (K093649)
Aesculap SterilContainer S (K093493)

DEVICE DESCRIPTION

The Aesculap SterilContainer S2 System is a reusable rigid container system that will allow for sterilization and storage of other medical devices. This container system is compatible for use in the following sterilization modalities:

- Dynamic-air removal steam (PreVac) (270°F for 4 minutes with 15 minute dry time)
- Gravity Steam (250°F for 30-60 minutes with 15 minute dry time)
- STERRAD 100S, STERRAD NX Standard, STERRAD NX Advanced, STERRAD 100NX Standard, STERRAD 100NX Flex Cycles
- STERIS V-PRO 60 Lumen, V-PRO 60 Non-Lumen, V-PRO 60 Flex, V-PRO maX Lumen, V-PRO maX Non-Lumen, V-PRO maX Flex cycles

The containers are perforated and made from anodized aluminum and utilize a single-use or reusable filter. The SterilContainer S2 System includes accessories such as mats, baskets, trays, instrument holders, organizers, filters, indicator cards and tamper proof locks.

Maintenance of Sterility

The maintenance of sterility for the load in this device is 360 days.

INDICATIONS FOR USE

The Aesculap SterilContainer S2 System is a reusable rigid sterilization container system intended to be used to enclose another medical device that is to be sterilized by a healthcare provider. 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 in the following sterilization modalities:

- Dynamic-air removal steam (PreVac) (Exposure: 270°F for 4 minutes with 15 minute dry time)
- Gravity Steam (Exposure: 250°F for 30-60 minutes with 15 minute dry time)
- STERRAD 100S, STERRAD NX Standard, STERRAD NX Advanced, STERRAD 100NX Standard, STERRAD 100NX Flex Cycles
- STERIS V-PRO 60 Lumen, V-PRO 60 Non-Lumen, V-PRO 60 Flex, V-PRO maX Lumen, V-PRO maX Non-Lumen, and V-PRO maX Flex Cycles.

The Aesculap SterilContainer S2 System includes accessories such as silicone mats and organizers, stainless steel baskets, trays, holders, sterilization indicator cards and tamper proof locks.

The attached table identifies the validated load configurations for each of the modalities.

Table 1. SterilContainer S2 System Validated Load Configurations

Sterilization Cycle	Container Size	Validated Load Configuration
Dynamic Air Removal Steam (PreVac)	Full	1 lumen with ≥ 3mm ID x ≤400mm L and a second lumen ≥ 3.8mm ID x ≤370mm L
	Three-Quarter	
	Half	
Gravity Steam	Full	Non lumen stainless steel instruments
	Three-Quarter	
	Half	
STERRAD 100S	Full	5 Stainless steel lumens ≥ 3.0mm ID and ≤400mm L
	Three-Quarter	
	Half	
STERRAD NX Standard	Full	5 Stainless steel lumens ≥ 2mm ID and ≤400mm L
	Three-Quarter	
	Half	
STERRAD NX Advanced	Full	1 Flexible lumen (≥ 1mm ID and ≤850mm L)
	Three-Quarter	
	Half	
STERRAD 100NX Standard	Full	5 Stainless steel lumens ≥ 0.7mm ID and ≤ 500mm L
	Three-Quarter	
	Half	

STERRAD 100NX Flex	Full Three-Quarter Half	1 Flexible Lumen 1mm ID and ≤850mm L
STERIS V-PRO 60 Lumen	Full Three-Quarter Half	Stainless steel lumens 1 lumen ≥ 0.77mm ID and ≤410mm L 1 lumen ≥ 1.2mm ID and ≤275mm L 1 lumen ≥ 1.8mm ID and ≤310mm L 1 lumen ≥ 2.8mm ID and ≤317mm L
STERIS V-PRO 60 Non-Lumen	Full Three-Quarter Half	Non lumen stainless steel instruments
STERIS V-PRO 60 Flex	Full Three-Quarter Half	1 flexible surgical endoscope or bronchoscope with a light cord (if not integral to endoscope) and mat without any additional load. The flexible endoscope may be a single or dual lumens that are >1mm ID and <990 mm L
STERIS V-PRO maX Lumen	Full Three-Quarter Half	Stainless steel lumens 1 lumen ≥ 0.77mm ID and ≤527mm L 1 lumen ≥ 1.2mm ID and ≤275mm L 1 lumen ≥ 1.8mm ID and ≤310mm L 1 lumen ≥ 2.8mm ID and ≤317mm L 1 lumen ≥ 3.0mm ID and ≤400mm L
STERIS V-PRO maX Non-Lumen	Full Three-Quarter Half	Non lumen stainless steel instruments
STERIS V-PRO maX Flex	Full Three-Quarter Half	2 flexible endoscopes with a light cord (if not integral to endoscope) and mat with no additional load. The scopes can have: a single lumen that is ≥ 1 mm ID and ≤ 1050 mm L or two lumens with one ≥ 1 mm ID and ≤ 990 mm L and the other ≥ 1 mm ID and ≤ 850 mm L OR 1 flexible endoscope with a light cord (if not integral to endoscope) and mat and additional non-lumened instruments. The scope can have: a single lumen that is ≥ 1 mm ID and ≤ 1050 mm L or two lumens with one ≥ 1 mm ID and ≤ 990 mm L and the other ≥ 1 mm ID and ≤ 850 mm L

Table 2. SterilContainer S2 System Configurations – Prevac Steam and Gravity Steam

Sterilization Method	**Container Size**	**Container Bottom Part #**	**Container Lid Part #**	**Total Loaded Container Weight***
Dynamic-air removal steam (PreVac) & Gravity Steam	Full Size - 4 ¼”	JS440	JS489	25 pounds
	Full Size - 5 ½”	JS441		
	Full Size - 6”	JS442		
	Full Size - 8”	JS444		

	Three-Quarter Size - 4 ¼ ”	JS740	JS789	25 pounds
	Three-Quarter Size - 5 ½”	JS741		
	Three-Quarter Size - 6”	JS742		
	Half Size - 4 ¼ ”	JS340	JS389	25 pounds
	Half Size - 5 ½	JS341		
	Half Size - 6”	JS342		

*Maximum load weight is 25 pounds or the maximum indicated weight for the sterilizer, whichever is less.

Table 3. Sterilization Cycle Compatible Accessories - Prevac Steam and Gravity Steam

Accessories	Compatible with Prevac Steam	Compatible with Gravity Steam
Stainless Steel baskets, basket lids, and dividers	Yes	Yes
Instrument Organization Syste h (Silicone and Stainless Steel racks, brackets, holders, and clamps)	Yes	Yes
Silicone mats	Yes	Yes

Table 4. SterilContainer S2 System Configurations – STERRAD Sterilization Systems

Sterilization Method	Container Size	Container Bottom Part #	Container Lid Part #	Total Loaded Container Weight
STERRAD 100 S	Full Size - 4 ¼”	JS440	JS489	13.95 pounds
	Full Size - 5 ½”	JS441		
	Full Size - 6”	JS442		
	Full Size - 8”	JS444		
	Three-Quarter Size - 4 ¼”	JS740	JS789	13.90 pounds
	Three-Quarter Size - 5 ½”	JS741		
	Three-Quarter Size - 6”	JS742		
	Half Size - 4 ½”	JS340	JS389	13.90 pounds
	Half Size - 5 ½	JS341		
	Half Size - 6”	JS342		
STERRAD NX Standard	Full Size - 4 ¼”	JS440	JS489	10.70 pounds
	Full Size - 5 ½”	JS441		
	Full Size - 6”	JS442		
	Full Size - 8”	JS444		
	Three-Quarter Size - 4 ¼”	JS740	JS789	10.70 pounds
	Three-Quarter Size - 5 ½”	JS741		
	Three-Quarter Size - 6”	JS742		
	Half Size - 4 ¼”	JS340	JS389	10.70 pounds
	Half Size - 5 ½	JS341		
	Half Size - 6”	JS342		

STERRAD NX Advanced	Full Size - 4 ¼”	JS440	JS489	10.70 pounds
	Full Size - 5 ½”	JS441		
	Full Size - 6”	JS442		
	Full Size - 8”	JS444		
	Three-Quarter Size - 4 ¼”	JS740	JS789	10.70 pounds
	Three-Quarter Size - 5 ½”	JS741		
	Three-Quarter Size - 6”	JS742		
	Half Size - 4 ¼”	JS340	JS389	10.70 pounds
	Half Size - 5 ½	JS341		
	Half Size - 6”	JS342		
STERRAD 100NX Standard	Full Size - 4 ¼”	JS440	JS489	21.45 pounds
	Full Size - 5 ½”	JS441		
	Full Size - 6”	JS442		
	Full Size - 8”	JS444		
	Three-Quarter Size - 4 ¼”	JS740	JS789	13.85 pounds
	Three-Quarter Size - 5 ½”	JS741		
	Three-Quarter Size - 6”	JS742		
	Half Size - 4 ¼”	JS340	JS389	13.85 pounds
	Half Size - 5 ½	JS341		
	Half Size - 6”	JS342		
STERRAD 100NX Flex	Full Size - 4 ¼”	JS440	JS489	10.95 pounds
	Full Size - 5 ½”	JS441		
	Full Size - 6”	JS442		
	Full Size - 8”	JS444		
	Three-Quarter Size - 4 ¼”	JS740	JS789	10.35 pounds
	Three-Quarter Size - 5 ½”	JS741		
	Three-Quarter Size - 6”	JS742		
	Half Size - 4 ¼”	JS340	JS389	10.35 pounds
	Half Size - 5 ½	JS341		
	Half Size - 6”	JS342		

Table 5. Sterilization Cycle Compatible Accessories – STERRAD Sterilization Systems

Accessories	Compatible with 100S	Compatible with NX Standard	Compatible with NX Advanced	Compatible with 100NX Standard	Compatible with 100NX Flex
Stainless Steel baskets, basket lids, and dividers	Yes	Yes	Yes	Yes	Yes
Instrument Organization System (Silicone and Stainless Steel racks, brackets, holders, and clamps)	Yes	Yes	Yes	Yes	Yes
Silicone mats	Yes	No	Yes	No	No

Table 6. SterilContainer S2 System Configurations – STERIS Sterilization Systems

Sterilization Method	Container Size	Container Bottom Part #	Container Lid Part #	Total Loaded Container Weight
STERIS V-PRO 60 Lumen	Full Size - 4 ¼"	JS440	JS489	11.1 pounds
	Full Size - 5 ½"	JS441		
	Full Size - 6"	JS442		
	Full Size - 8"	JS444		
	Three-Quarter Size - 4 ¼"	JS740	JS789	9.6 pounds
	Three-Quarter Size - 5 ½"	JS741		
	Three-Quarter Size - 6"	JS742		
	Half Size - 4 ¼"	JS340	JS389	9.6 pounds
	Half Size - 5 ½	JS341		
	Half Size - 6"	JS342		
STERIS V-PRO 60 Non-Lumen	Full Size - 4 ¼"	JS440	JS489	12.0 pounds
	Full Size - 5 ½"	JS441		
	Full Size - 6"	JS442		
	Full Size - 8"	JS444		
	Three-Quarter Size - 4 ¼"	JS740	JS789	12.0 pounds
	Three-Quarter Size - 5 ½"	JS741		
	Three-Quarter Size - 6"	JS742		
	Half Size - 4 ¼"	JS340	JS389	12.0 pounds
	Half Size - 5 ½	JS341		
	Half Size - 6"	JS342		
STERIS V-PRO 60 Flex	Full Size - 4 ¼"	JS440	JS489	1 flexible surgical endoscope or bronchoscope with a light cord (if not integral to endoscope) and mat without any additional load. The flexible endoscope may be a single or dual lumens that are >1mm ID and <990 mm L
	Full Size - 5 ½"	JS441		
	Full Size - 6"	JS442		
	Full Size - 8"	JS444		
	Three-Quarter Size - 4 ¼"	JS740	JS789	1 flexible surgical endoscope or bronchoscope with a light cord (if not integral to endoscope) and mat without any additional load. The flexible endoscope may be a single or dual lumens that are >1mm ID and <990 mm L
	Three-Quarter Size - 5 ½"	JS741		
	Three-Quarter Size - 6"	JS742		

	Half Size - 4 ¼”	JS340	JS389	1 flexible surgical endoscope or bronchoscope with a light cord (if not integral to endoscope) and mat without any additional load. The flexible endoscope may be a single or dual lumens that are >1mm ID and <990 mm L
	Half Size - 5 ½	JS341		
	Half Size - 6”	JS342		
STERIS V-PRO maX Lumen	Full Size - 4 ¼”	JS440	JS489	11.1 pounds
	Full Size - 5 ½”	JS441		
	Full Size - 6”	JS442		
	Full Size - 8”	JS444		
	Three-Quarter Size - 4 ¼”	JS740	JS789	9.6 pounds
	Three-Quarter Size - 5 ½”	JS741		
	Three-Quarter Size - 6”	JS742		
	Half Size - 4 ¼”	JS340	JS389	9.6 pounds
	Half Size - 5 ½	JS341		
	Half Size - 6”	JS342		
STERIS V-PRO maX Non-Lumen	Full Size - 4 ¼”	JS440	JS489	18.6 pounds
	Full Size - 5 ½”	JS441		
	Full Size - 6”	JS442		
	Full Size - 8”	JS444		
	Three-Quarter Size - 4 ¼”	JS740	JS789	18.6 pounds
	Three-Quarter Size - 5 ½”	JS741		
	Three-Quarter Size - 6”	JS742		
	Half Size - 4 ¼”	JS340	JS389	18.6 pounds
	Half Size - 5 ½	JS341		
	Half Size - 6”	JS342		
STERIS V-PRO maX Flex	Full Size - 4 ¼”	JS440	JS489	10.3 pounds
	Full Size - 5 ½”	JS441		
	Full Size - 6”	JS442		
	Full Size - 8”	JS444		
	Three-Quarter Size - 4 ¼”	JS740	JS789	10.0 pounds
	Three-Quarter Size - 5 ½”	JS741		
	Three-Quarter Size - 6”	JS742		
	Half Size - 4 ¼”	JS340	JS389	10.0 pounds
	Half Size - 5 ½	JS341		
	Half Size - 6”	JS342		

Table 7. Sterilization Cycle Compatible Accessories – STERIS Sterilization Systems

Accessories	Compatible with V-PRO 60 Lumen	Compatible with V-PRO 60 Non-Lumen	Compatible with V-PRO 60 Flex	Compatible with V-PRO maX Lumen	Compatible with V-PRO maX Non-Lumen	Compatible with V-PRO maX Flex
Stainless Steel baskets, basket lids, and dividers	Yes	*Yes*	Yes	Yes	Yes	Yes
Instrument Organization System (Silicone and Stainless Steel racks, brackets, holders, and clamps)	Yes	Yes	Yes	Yes	Yes	Yes
Silicone mats	No	No	No	No	No	No

TECHNOLIGICAL CHARACTERISTICS (compared to predicate device)

Shown below is the Aesculap SterilContainer™ S2 System comparison with the predicate device.

	Subject Device - Aesculap SterilContainer™ S2 System (K182414)	**Primary Predicate – Aesculap SterilContainer™ (K792558)**	**Reference Device – Aesculap SterilContainer™S (K093649)**	**Reference Device – Aesculap SterilContainer™S (K093493)**	
Intended Use	A device intended to be used to enclose another medical device that is to be sterilized by a health care provider. It is intended to allow sterilization of the enclosed medical device and also to maintain sterility of the enclosed device until used.	A device intended to be used to enclose another medical device that is to be sterilized by a health care provider. It is intended to allow sterilization of the enclosed medical device and also to maintain sterility of the enclosed device until used.	A device intended to be used to enclose another medical device that is to be sterilized by a health care provider. It is intended to allow sterilization of the enclosed medical device and also to maintain sterility of the enclosed device until used.	A device intended to be used to enclose another medical device that is to be sterilized by a health care provider. It is intended to allow sterilization of the enclosed medical device and also to maintain sterility of the enclosed device until used.	Same
Sterilization Modalities	Prevac Steam (Exposure: 270°F for 4 minutes with 15 minute dry time) Gravity Steam (Exposure: 250°F for 30-60 minutes with 15 minute dry time) STERRAD 100S STERRAD NX Standard STERRAD NX Advanced STERRAD 100NX Standard STERRAD 100NX Flex STERIS V-PRO 60 Lumen STERIS V-PRO 60 Non-Lumen STERIS V-PRO 60 Flex STERIS V-PRO maX Lumen STERIS V-PRO maX Non-Lumen STERIS V-PRO maX Flex	PreVac Steam (270°F for 4 minutes with 15 minute dry time) Gravity Steam (250°F for 30-60 minutes with 15 minute dry time)	V-PRO 1 V-PRO Plus	STERRAD 200 STERRAD NX STERRAD 100NX	Similar
Material of Construction	Container: Anodized aluminum Lid: Anodized aluminum Gasket: Silicone	Container: Anodized aluminum Lid: Anodized aluminum Gasket: Silicone	Container: Non-Anodized Aluminum Lid: Non-Anodized Aluminum Gasket: Silicone	Container: Non-Anodized Aluminum Lid: Non-Anodized Aluminum Gasket: Silicone	Same
Filter Type	Single use and reusable	Single use and reusable	Single use	Single use	Same
Filter material	Single use: Paper (cellulose) or polypropylene Reusable: PTFE	Single use: Paper (cellulose) or polypropylene Reusable: PTFE	Single use: Polypropylene	Single use: Polypropylene	Same
Container Design	Perforated bottom with perforated lid	Solid or perforated bottom with perforated lid	Perforated bottom with perforated lid	Perforated bottom with perforated lid	Same
Vent to Volume ratio	1.4 – 3.4	0.69 – 3.42	1.4 – 3.4	1.4 – 3.4	Similar
Sizes	Full size Three-Quarter Size Half Size	Full size Three-Quarter Size Half Size Mini/XL Mini	Full size Three-Quarter Size Half Size Mini/XL Mini	Full size Three-Quarter Size Half Size Mini/XL Mini	Same
Accessories	Silicone mats, baskets, trays, and racks.	Silicone mats, baskets, trays, and racks.	Silicone mats, baskets, trays, and racks.	Silicone mats, baskets, trays, and racks.	Same
Maintenance of Sterility	360 days	360 days	360 days	360 days	Same

Summary of Non-Clinical Testing

Non-clinical testing was conducted to verify the performance of the subject device. The testing provided below demonstrates that the subject device met the acceptance criteria of each test below.

Performance Testing	Purpose	Acceptance Criteria	Results
Sterilization Efficacy	To determine sterilization effectiveness of test device after processing in a sterilization cycle.	A sterility assurance level (SAL) of 10^{-6} will be achieved post sterilization using the BI overkill method and half cycle validation. Biological indicators must be negative for growth after incubation period.	Pass
Simulated Use	To determine the effective sterilization of flexible scopes when used with the test device.	A minimum of 1.0×10^6 spores contained within organic soil representative of actual use conditions are killed during defined sterilization cycle. Biological indicators must be negative for growth after incubation period.	Pass
Microbial Aerosol Challenge	To analyze the package integrity and microbial barrier properties of the test device.	Post sterilization, the container load maintains sterility after exposure to a defined amount of aerosol microorganisms. No presence of growth after incubation period.	Pass
Maintenance of Sterility	To demonstrate that a processed test device can maintain a sterile barrier for a defined period of time	Sterility of container contents is maintained after processing for 360 days under conditions which simulate hospital sterile package handling and storage conditions. Biological indicators must be negative for growth after incubation period.	Pass
Reusable Filter	To demonstrate sterilization effectiveness after determined number of sterilization and wash cycles.	Sterility Assurance Level (SAL) of 10^{-6} will be achieved after 2200 sterilization and washing cycles using half cycle testing with biological indicators to demonstrate a 6 log reduction.	Pass
Material Compatibility	To assess effects of full use cycles on device components and their intended functionality.	No degradation or impact to functionality at the completion multiple sterilization cycles.	Pass
Cytotoxicity	To determine the potential of a test device to cause cytotoxicity.	Testing completed in accordance with ISO 10993-5: 2009 to demonstrate no significant cytotoxic reaction after exposure to sterilant. Using the ISO Elution Method, the response to the article is not greater than 2 (mild reactivity).	Pass

CONCLUSION

The conclusions drawn from the nonclinical tests that demonstrate that the Aesculap(R) SterilContainer™ S2 System is as safe, as effective, and performs as well as or better than the legally marketed predicate device, Aesculap SterilContainer System (K792558).