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

August 18, 2015

Aesculap, Inc.
Denise R. Adams, RAC
Regulatory Affairs Specialist
3773 Corporate Parkway
Center Valley, PA 18034

Re: K143729
Trade/Device Name: SterilContainer™ *S*
Regulation Number: 21 CFR 880.6850
Regulation Name: Sterilization wrap containers, trays, cassettes & other accessory
Regulatory Class: II
Product Code: KCT
Dated: July 22, 2015
Received: July 23, 2015

Dear Ms. Adams:

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.
Clinical Deputy Director
DAGRID/ODE/CDRH FOR

Erin I. Keith, M.S.
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)*
K143729

Device Name
SterilContainer S

Indications for Use *(Describe)*

The SterilContainer *S* 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 V-PRO 60 Low Temperature Sterilization System's Lumen, Non Lumen and Flexible Cycles. The SterilContainer *S* includes accessories such as silicone mats, baskets, trays, racks, eyepiece holders and sleeve holders.

The SterilContainer *S* was demonstrated to maintain the sterility of its contents for 180 days following successful sterilization.

V-PRO 60 Sterilizer Lumen Cycle

Lid	Bottom	Description	Total loaded container weight (lbs)	Intended Container Load

JM489	JM440	Full Size 90mm (4 ¼")*	21.46	• Lumened and non-lumened devices with diffusion-restricted spaces such as the hinged portion of forceps and scissors
				• Medical devices, including single, dual and triple channeled rigid and semi-rigid endoscopes, with the following configurations:
				  • single or dual lumen devices with stainless lumen(s) that is (are) ≥ 0.77 mm internal diameter (ID) and ≤ 410 mm length
				  • triple lumen devices with stainless steel lumens that are
				  ≥ 1.2 mm ID and ≤ 275 mm length
				  ≥ 1.8 mm ID and ≤ 310 mm length
				  ≥ 2.8 mm ID and ≤ 317 mm length

	JM441	Full Size 120mm (5 ½")*	21.46	
	JM442	Full Size 135mm (6")*	21.46	
JM789	JM740	¾ Size 90mm (4 ¼")*	13.85	
	JM741	¾ Size 120mm (5 ½")*	13.85	
	JM742	¾ Size 135mm (6")*	13.85	
JM389	JM340	½ Size 90mm (4 ¼")*	13.85	
	JM341	½ Size 120mm (5 ½")*	13.85	
	JM342	½ Size 135mm (6")*	13.85	
JM020	JM021	Extra Long Mini 73mm (3")**	7.65	
JM174	JM188	Mini 67mm (2 ⅝")**	7.65	

* The validation chamber load consisted of one container containing a basket and basket lid, mat, accessories, 12 lumens, and metal and non-metal medical devices

**The validation chamber load consisted of two containers containing a basket and basket lid, mat, accessories, and metal and non-metal medical devices for a total chamber load weight of 15.30 lbs. Each container held six (6) lumens for a total of 12 total lumens per load.

V-PRO 60 Sterilizer Non Lumen Cycle

Lid	Bottom	Description	Total loaded container weight (lbs)	Intended Container Load
JM489	JM440	Full Size 90mm (4 ¼")*	20.0	Non-lumened devices including devices with stainless steel or titanium diffusion-restricted spaces such as the hinged portion of forceps and scissors.
	JM441	Full Size 120mm (5 ½")*	20.0	
	JM442	Full Size 135mm (6")*	20.0	
JM789	JM740	¾ Size 90mm (4 ¼")*	13.85	
	JM741	¾ Size 120mm (5 ½")*	13.85	
	JM742	¾ Size 135mm (6")*	13.85	
JM389	JM340	½ Size 90mm (4 ¼")*	13.85	
	JM341	½ Size 120mm (5 ½")*	13.85	
	JM342	½ Size 135mm (6")*	13.85	
JM020	JM021	Extra Long Mini 73mm (3")**	7.64	
JM174	JM188	Mini 67mm (2 ⅝")**	7.64	

* The validation chamber load consisted of one container with a basket and basket lid, mat, accessories, and metal and non-metal medical devices

**The validation chamber load consisted of two containers with a basket and basket lid, mat, accessories, and metal and non-metal medical devices for a total chamber load weight of 15.30 lbs.

V-PRO 60 Sterilizer Flexible Cycle

Lid	Bottom	Description*	Total loaded container weight (lbs)	Intended Container Load
JM489	JM440	Full Size 90mm (4 ¼")	21.46	One flexible surgical endoscope or bronchoscope with a light cord (if not integral to the endoscope) and mat without any additional load. The flexible endoscopes may contain: • single or dual lumen devices with lumens that are ≥ 1 mm ID and ≤ 990 mm length
	JM441	Full Size 120mm (5 ½")	21.46	
	JM442	Full Size 135mm (6")	21.46	
JM789	JM740	¾ Size 90mm (4 ¼")	13.85	
	JM741	¾ Size 120mm (5 ½")	13.85	
	JM742	¾ Size 135mm (6")	13.85	
JM389	JM340	½ Size 90mm (4 ¼")	13.85	
	JM341	½ Size 120mm (5 ½")	13.85	
	JM342	½ Size 135mm (6")	13.85	

* The validation chamber load consisted of one container with a basket and lid, mat, accessories, three (3) 1 x 1000mm lumens, one flexible endoscope, and one light cable.

V-PRO 60 Sterilizer Compatible SterilContainer *S* Accessories

Accessories	V-PRO 60
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)
K143729

SPONSOR:	Aesculap, Inc. 3773 Corporate Parkway Center Valley, PA 18034 Establishment Registration Number: 2916714
CONTACT:	Denise R. Adams, RAC 610-984-9076 (phone) 610-791-6882 (fax) denise.adams@aesculap.com (email)
DATE:	July 7, 2015
TRADE NAME:	SterilContainer™ *S*
COMMON NAME:	Sterilization container
CLASSIFICATION NAME:	Sterilization wrap containers, trays, cassettes & other accessories (21 CFR 880.6850, Product Code KCT)
DEVICE CLASS:	Class II per 21 CFR 880.6850
PREDICATE:	K093649, Aesculap SterilContainer *S* cleared for use in V-PRO 1 and V-PRO 1 Plus

DEVICE DESCRIPTION

The SterilContainer *S* is a container system that will allow for sterilization and storage of medical devices. This container system is for use in low-temperature sterilization technology such as with the Steris V-PRO 60 Sterilization System. The SterilContainer *S* rigid containers are made from non-anodized Aluminum and utilize disposable (single use) polypropylene filters. The SterilContainer *S* includes accessories such as mats, baskets, trays, holders, organizers, filters, indicator cards and tamper-evident locks.

INDICATIONS FOR USE

The SterilContainer *S* 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 V-PRO 60 Low Temperature Sterilization System's Lumen, Non Lumen and Flexible Cycles. The SterilContainer *S* includes accessories such as silicone mats, baskets, trays, racks, eyepiece holders and sleeve holders.

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The SterilContainer *S* was demonstrated to maintain the sterility of its contents for 180 days following successful sterilization.

V-PRO 60 Sterilizer Lumen Cycle

Lid	Bottom	Description	Total loaded container weight (lbs)	Intended Container Load
JM489	JM440	Full Size 90mm (4 ¼")*	21.46	• Lumened and non-lumened devices with diffusion-restricted spaces such as the hinged portion of forceps and scissors • Medical devices, including single, dual and triple channeled rigid and semi-rigid endoscopes, with the following configurations: • single or dual lumen devices with stainless lumen(s) that is (are) ≥ 0.77 mm internal diameter (ID) and ≤ 410 mm length • triple lumen devices with stainless steel lumens that are ≥ 1.2 mm ID and ≤ 275 mm length ≥ 1.8 mm ID and ≤ 310 mm length ≥ 2.8 mm ID and ≤ 317 mm length
	JM441	Full Size 120mm (5 ½")*	21.46	
	JM442	Full Size 135mm (6")*	21.46	
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JM020	JM021	Extra Long Mini 73mm (3")**	7.65	
JM174	JM188	Mini 67mm (2 ⅝")**	7.65	

* The validation chamber load consisted of one container containing a basket and basket lid, mat, accessories, 12 lumens, and metal and non-metal medical devices

**The validation chamber load consisted of two containers containing a basket and basket lid, mat, accessories, and metal and non-metal medical devices for a total chamber load weight of 15.30 lbs. Each container held six (6) lumens for a total of 12 total lumens per load

V-PRO 60 Sterilizer Non Lumen Cycle

Lid	Bottom	Description	Total loaded container weight (lbs)	Intended Container Load
JM489	JM440	Full Size 90mm (4 ¼")*	20.0	Non-lumened devices including devices with stainless steel or titanium diffusion-restricted spaces such as the hinged portion of forceps and scissors.
	JM441	Full Size 120mm (5 ½")*	20.0	
	JM442	Full Size 135mm (6")*	20.0	
JM789	JM740	¾ Size 90mm (4 ¼")*	13.85	
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V-PRO 60 Sterilizer Flexible Cycle

Lid	Bottom	Description*	Total loaded container weight (lbs)	Intended Container Load
JM489	JM440	Full Size 90mm (4 ¼")	21.46	One flexible surgical endoscope or bronchoscope with a light cord (if not integral to the endoscope) and mat without any additional load. The flexible endoscopes may contain: • single or dual lumen devices with lumens that are ≥ 1 mm ID and ≤ 990 mm length
	JM441	Full Size 120mm (5 ½")	21.46	
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* The validation chamber load consisted of one container with a basket and lid, mat, accessories, three (3) 1 x 1000mm lumens, one flexible endoscope, and one light cable.

V-PRO 60 Sterilizer Compatible SterilContainer *S* Accessories

Accessories	V-PRO 60
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

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TECHNOLIGICAL CHARACTERISTICS (compared to predicates)
The SterilContainer *S* is for use in low-temperature sterilization technology such as the Steris V-PRO 60. The SterilContainer *S* is the same container system as was cleared in K093649. The materials and design have not changed.

System	**SterilContainer *S* (K143729)**	**SterilContainer *S* (K093649)**
Intended Use	The SterilContainer *S* 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 V-PRO 60 Low Temperature Sterilization System's Lumen, Non Lumen and Flexible Cycles. The SterilContainer *S* includes accessories such as silicone mats, baskets, trays, racks, eyepiece holders and sleeve holders.	The Aesculap Sterilcontainer *S* is a reusable 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 with the V-PRO 1 and V-PRO Plus Systems.
Sterilizer	Steris V-PRO 60	Steris V-PRO 1 and V-PRO 1 Plus
Material	Non-anodized aluminum	Non-anodized aluminum
Container type	Perforated	Perforated
Filter type	Polypropylene	Polypropylene

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PERFORMANCE DATA

The SterilContainer *S* has been fully validated for the Steris V-PRO 60 Sterilizer. These validations were conducted by a qualified testing laboratory. The performance testing demonstrates substantial equivalence to the predicate devices.

Performance Properties	Results
Sterilization Efficacy	Testing demonstrated a 6 log reduction to no growth in a half cycle validation. This testing supports a sterility assurance level (SAL) of 10^{-6} in a full cycle validation.
Whole Package Microbial Aerosol Challenge	After exposure to a defined amount of aerosol microorganisms contents maintained sterility
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	After 100 cycles of processing no visible or functional changes were observed
Simulated Use	A worst case dual channel flexible endoscope was reproducibly sterilized under worst case simulated use testing conditions in the Flexible Cycle.

CONCLUSION

Based on the nonclinical tests performed the subject device is as safe, as effective and performs at least as safely and effectively as the legally marketed predicate device (K093649), Class II (21 CFR 880.6850), product code KCT.

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