December 21, 2018

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

Re: K182032
Trade/Device Name: SterilContainer S System
Regulation Number: 21 CFR 880.6850
Regulation Name: Sterilization Wrap
Regulatory Class: Class II
Product Code: KCT
Dated: November 20, 2018
Received: November 23, 2018

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. 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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Elizabeth F. Claverie -S

For Tina Kiang, Ph.D.
Acting Director
Division of Anesthesiology,
General Hospital, Respiratory,
Infection Control, and Dental Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

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

510(k) Number *(if known)*
K182032

Device Name
SterilContainer™ S System

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 flexible endoscopes and accessories, cables, and camera heads. 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 STERRAD 100NX DUO Cycle. The SterilContainer S System includes accessories such as silicone mats, baskets, trays, racks, filters, indicator cards, locks, and instrument holders.

Validation testing for event related sterility maintenance has been conducted for up to 365 days.

Table 1: Validated STERRAD 100NX DUO Cycle Load Configurations

Load Configuration	Container # 1	Container # 2
1	• 135mm Full Size Container Bottom • Full Size Container Lid • Full Size Basket • Full Size Mat • Flexible Endoscope (1.2 mm x 785 mm) • Guide Cable (1x)	• 135mm Full Size Container Bottom • Full Size Container Lid • Full Size Basket • Full Size Mat • Flexible Endoscope (1.2 mm x 785 mm) • Guide Cable (2x)
2	• 187mm Full Size Container Bottom • Full Size Container Lid • Full Size Basket • Full Size Mat • Flexible Endoscope (1.2 mm x 785 mm) • Guide Cable (2x)	• N/A – Top shelf is removed to allow the container to fit in the chamber
3	• 90mm Full Size Container Bottom • Full Size Container Lid • Full Size Basket • Full Size Mat • Flexible Endoscope (1.2 mm x 785 mm) • Guide Cable (2x)	• 135mm Half Size Container Bottom • Half Size Container Lid • Half Size Basket • Half Size Mat • Camera Head for Endoscope

Table 2: STERRAD 100NX DUO Compatible SterilContainer S Container Systems

Lid	Bottom	Description	Container Load Weight *
JM489	JM440	Full Size 90mm (4 ¼")	13.2 lbs total weight. (1 or 2 shelves based on container)
	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")	
JM389	JM340	½ Size 90mm (4 ¼")	
	JM341	½ Size 120mm (5 ½")	
	JM342	½ Size 135mm (6")	
	JM344	½ Size 187mm (8")	

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

Table 3: STERRAD 100NX DUO Cycle Compatible Accessories

Accessories	STERRAD 100NX DUO Cycle
Stainless Steel baskets, basket lids, and dividers	Yes
Instrument Organization System (Silicone and Stainless Steel racks, brackets, instrument holders, and clamps)	Yes
Silicone mats	Yes
Stainless Steel racks, trays, instrument holders, clamps, brackets, tamper-proof locks, indicator cards 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 for use in the STERRAD 100NX DUO Cycle

Dec 13, 2018

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

CONTACT: Paul Amudala
Regulatory Affairs Specialist
610-984-9303 (phone)
610-791-6882 (fax)

TRADE NAME: SterilContainer S System

COMMON NAME: Sterilization Container Wrap

CLASSIFICATION NAME: Sterilization Wrap

REGULATION NUMBER: 21 CFR 880.6850

PRODUCT CODE: KCT

DEVICE CLASS: Class II

PREDICATE DEVICE

K093493 - SterilContainer™ S System for use in STERRAD 200, STERRAD NX (STANDARD (Std.) & ADVANCED (Adv.) and STERRAD 100NX (Std. & FLEX)

REFERENCE DEVICE

K142970- SterilContainer™ *S* for use in STERRAD 100NX EXPRESS Cycle via K142970.

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 STERRAD 100NX DUO 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, instrument 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 flexible endoscopes and accessories, cables, and camera heads. 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 STERRAD 100NX DUO Cycle. The SterilContainer S System includes accessories such as silicone mats, baskets, trays, racks, filters, indicator cards, locks, and instrument holders.

Validation testing for event related sterility maintenance has been conducted for up to 365 days.

Table 1: Validated STERRAD 100NX DUO Cycle Load Configurations

Load Configuration	Container # 1	Container # 2
1	• 135mm Full Size Container Bottom • Full Size Container Lid • Full Size Basket • Full Size Mat • Flexible Endoscope (1.2 mm x 785 mm) • Guide Cable (1x)	• 135mm Full Size Container Bottom • Full Size Container Lid • Full Size Basket • Full Size Mat • Flexible Endoscope (1.2 mm x 785 mm) • Guide Cable (2x)
2	• 187mm Full Size Container Bottom • Full Size Container Lid • Full Size Basket • Full Size Mat • Flexible Endoscope (1.2 mm x 785 mm) • Guide Cable (2x)	• N/A – Top shelf is removed to allow the container to fit in the chamber
3	• 90mm Full Size Container Bottom • Full Size Container Lid • Full Size Basket • Full Size Mat • Flexible Endoscope (1.2 mm x 785 mm) • Guide Cable (2x)	• 135mm Half Size Container Bottom • Half Size Container Lid • Half Size Basket • Half Size Mat • Camera Head for Endoscope

Table 2: STERRAD 100NX DUO Compatible SterilContainer S Container Systems

Lid	Bottom	Description	Container Load Weight *
JM489	JM440	Full Size 90mm (4 ¼”)	13.2 lbs total weight. (1 or 2 shelves based on container)
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*Loads containing a flexible endoscope or bronchoscope should follow Table 1 recommendations

Table 3: STERRAD 100NX DUO Compatible Accessories

Accessories	STERRAD 100NX DUO Cycle
Stainless Steel baskets, basket lids, and dividers	Yes
Instrument Organization System (Silicone and Stainless Steel racks, brackets, instrument holders, and clamps)	Yes
Silicone mats	Yes
Stainless Steel racks, trays, instrument holders, clamps, brackets, tamper-proof locks, indicator cards and platforms	Yes

TECHNOLIGICAL CHARACTERISTICS COMPARISON TABLE

The SterilContainer S System for proposed use in the STERRAD 100NX DUO is the same container system that was cleared in K093493 & K142970. The materials and design have not changed.

System	SterilContainer S System (K182032)	SterilContainer S System (K093493) Primary Predicate	SterilContainer S System (K142970) Reference Device	Comparison
Sterilization process	STERRAD 100NX DUO	STERRAD 200 , STERRAD NX & Adv. , STERRAD 100 NX Std. & FLEX Cycle	STERRAD 100NX EXPRESS	Different
Material	Non-anodized aluminum	Non-anodized aluminum	Non-anodized aluminum	Same
Container type	Perforated	Perforated	Perforated	Same
Filter type	Polypropylene	Polypropylene	Polypropylene	Same
Gasket	Silicone	Silicone	Silicone	Same
Sizes	Full, ½, ¾	Full, ½, ¾, ¼, XL Mini	Full,½	Similar
Accessories	Stainless Steel baskets, basket lids, dividers, racks, trays, holders clamps; instrument organization systems; silicone mats; tamper proof locks; indicator cards	Stainless Steel baskets, basket lids, dividers, racks, trays, holders clamps; instrument organization systems; silicone mats; tamper proof locks; indicator cards	Stainless Steel baskets, basket lids, dividers, racks, trays, holders clamps; instrument organization systems; silicone mats; tamper proof locks; indicator cards	Same
Reuse	Reusable	Reusable	Reusable	Same

NON-CLINICAL PERFORMANCE DATA

The Aesculap SterilContainer S System has been validated for the STERRAD 100NX DUO Cycle. These validations were conducted by a qualified testing laboratory. The performance testing demonstrates that the device meets the acceptance criteria for each test.

Performance Testing	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.
Maintenance of Sterility	Maintenance Sterility for the proposed devices remains unchanged and continues to provide an effective barrier for maintaining sterility of the contents after sterilization for 365 days event related storage under conditions which simulate hospital sterile package handling and storage conditions still applies for the DUO cycle.
Simulated Use	Testing demonstrated that a 6-log reduction of G. stearothermophilus suspended in artificial soil medium is achieved for the Aesculap, Inc. SterilContainer S Containers when processed through a full cycle in the STERRAD 100NX DUO Cycle in healthcare facilities.
Inactivation Kinetics	No growth was observed from three different injection doses for load configuration 1, 2 and 3 respectively.
Aerosol Challenge	The Aerosol challenge remains unchanged from the predicates as the container as well as the gaskets of the container remain the same as cleared in predicates. Predicate device data is still relevant for the proposed device.
Material Compatibility	Material Compatibility test data has not changed and remains the same as cleared in predicate.
Biocompatibility	The biocompatibility of the container remains unchanged from the predicates as the materials of the container remains the same as cleared in the predicate.

CONCLUSION

The non-clinical testing demonstrates that the SterilContainer S System for use in the STERRAD 100NX DUO Cycle is as safe, as effective and performs as well as or better than the legally marketed predicate device, the Aesculap SterilContainer S System for use in the STERRAD 200, STERRAD NX (Std. & Adv.) and STERRAD 100NX (Std. and Flex) Cycles (K093493) .