March 17, 2020

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

Re: K193582
Trade/Device Name: SterilContainer S2 System
Regulation Number: 21 CFR 880.6850
Regulation Name: Sterilization Wrap
Regulatory Class: Class II
Product Code: KCT
Dated: December 19, 2019
Received: December 23, 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 CAPT Elizabeth Claverie, M.S.
Assistant Director
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*

K193582

Device Name

Aesculap SterilContainer S2™ System

Indications for Use *(Describe)*

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:

- Ethylene Oxide
- STERRAD 100NX DUO cycle
- STERIZONE VP4

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
EtO (130°F, 60 minute exposure, ≥50% RH 725mg/L gas pressure)	Full Three-Quarter Half	(1) lumen (≥ 3mm ID x ≤ 400mm L) AND (1) lumen (≥ 3.8mm ID x ≤ 370 mm L)
STERRAD 100NX DUO *(bottom shelf only)*	Full Three-Quarter Half	Flexible scope (≥ 1mm ID x ≤ 850mm L)
STERIZONE VP4 Validated Loads 1 & 2 (Based on Sterizone Load #7)	Full Three-Quarter Half	Non Lumened Instruments
STERIZONE VP4 Validated Load 3 (Based on Sterizone Load #8)	JS440 (base) + JS489 (lid)	(1) Single Channel Flexible Scope (≥1mm ID x ≤ 850mm L) OR (1) Dual Channel Flexible Scope (≥1mm ID x ≤850 mm L and ≥1 mm ID x ≤ 989mm L)
STERIZONE Validated Load 4 (Based on Sterizone Load #4)	JS440 (base) + JS489 (lid)	(1) Semi-rigid dual channel scope (≥0.7mm ID x ≤500mm L and ≥1.1mm ID x ≤500mm L) AND one of the following: (4) Stainless steel lumens (≥ 5.5mm ID x ≤ 166mm L; ≥ 7mm ID x ≤ 105mm L; ≥ 7.0mm ID x ≤ 227mm L; ≥ 7.8mm ID x ≤ 198mm L) OR (2) Stainless steel lumens (≥ 4mm ID x ≤ 370mm L; ≥ 2mm ID x ≤ 152mm L) OR (3) Stainless steel lumens (≥ 2.2mm ID x ≤ 173mm L; ≥ 4.7mm ID x ≤ 270mmL ; ≥ 4mm ID x ≤ 445mm L)

Table 2. SterilContainer S2 System Load Weights

Sterilization Method	Container Size	Container Bottom Part #	Container Lid Part #	Total Loaded Container (lb)
EtO	Full Size - 4 ¼"	JS440	JS489	25
	Full Size - 5 ½"	JS441		
	Full Size - 6"	JS442		
	Full Size - 8"	JS444		
	Three-Quarter Size - 4 ¼"	JS740	JS789	25
	Three-Quarter Size - 5 ½"	JS741		
	Three-Quarter Size - 6"	JS742		
	Three-Quarter Size - 8"	JS744*		
	Half Size - 4 ½"	JS340	JS389	25
	Half Size - 5 ½	JS341		
	Half Size - 6"	JS342		
STERRAD 100NX DUO	Full Size - 4 ¼"	JS440	JS489	10.97
	Full Size - 5 ½"	JS441		
	Full Size - 6"	JS442		
	Full Size - 8"	JS444		
	Three-Quarter Size - 4 ¼"	JS740	JS789	10.04
	Three-Quarter Size - 5 ½"	JS741		
	Three-Quarter Size - 6"	JS742		
	Half Size - 4 ¼"	JS340	JS389	11.7
	Half Size - 5 ½	JS341		
	Half Size - 6"	JS342		
STERIZONE Validated Loads 1 & 2 (Based on Sterizone Load #7)	Full Size - 4 ¼"	JS440	JS489	25
	Full Size - 5 ½"	JS441		
	Full Size - 6"	JS442		
	Full Size - 8"	JS444		
	Three-Quarter Size - 4 ¼"	JS740	JS789	25
	Three-Quarter Size - 5 ½"	JS741		
	Three-Quarter Size - 6"	JS742		
	Half Size - 4 ¼"	JS340	JS389	25
	Half Size - 5 ½	JS341		
	Half Size - 6"	JS342		
	Half Size - 5 ½	JS341		
	Half Size - 6"	JS342		
STERIZONE Validated Load 3 (Based on Sterizone Load #8)	Full Size - 4 ¼"	JS440	JS489	See load configuration in table 1 above
STERIZONE Validated Load 4 (Based on Sterizone Load #4)	Full Size - 4 ¼"	JS440	JS489	See load configuration in table 1 above

*JS744 is for use in Ethylene Oxide only.

Table 3. Sterilization Cycle Compatible Accessories

Accessories	Compatible with Ethylene Oxide	Compatible with STERRAD DUO	Compatible with STERIZONE VP4
Stainless Steel baskets, basket lids, and dividers	Yes	Yes	Yes
Instrument Organization System (Silicone and Stainless Steel racks, brackets, holders, and clamps)	Yes	Yes	Yes
Silicone mats	Yes	No	Yes
Tamper Evident locks and indicator cards	Yes	Yes	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)

Aesculap SterilContainer S2 System for
Ethylene Oxide, STERIZONE VP4, STERRAD 100NX DUO
March 11, 2020

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 per 21 CFR 880.6850

PREDICATE DEVICES

Aesculap SterilContainer S2 System - K182414 (Primary),
SterilContainer S System - K162815
SterilContainer System - K112671

DEVICE DESCRIPTION

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

- Ethylene Oxide
- STERRAD 100NX DUO cycle
- STERIZONE VP4

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

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:

- Ethylene Oxide
- STERRAD 100NX DUO cycle
- STERIZONE VP4

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
EtO (130°F, 60 minute exposure, ≥50% RH 725mg/L gas pressure)	Full	(1) lumen (≥ 3mm ID x ≤ 400mm L) AND (1) lumen (≥ 3.8mm ID x ≤ 370 mm L)
	Three-Quarter	
	Half	
STERRAD 100NX DUO *(bottom shelf only)*	Full	Flexible scope (≥ 1mm ID x ≤ 850mm L)
	Three-Quarter	
	Half	
STERIZONE VP4 Validated Loads 1 & 2 (Based on Sterizone Load #7)	Full	Non Lumened Instruments
	Three-Quarter	
	Half	
STERIZONE VP4 Validated Load 3 (Based on Sterizone Load #8)	JS440 (base) + JS489 (lid)	(1) Single Channel Flexible Scope (≥1mm ID x ≤ 850mm L) OR (1) Dual Channel Flexible Scope (≥1mm ID x ≤850 mm L and ≥1 mm ID x ≤ 989mm L)
STERIZONE Validated Load 4 (Based on Sterizone Load #4)	JS440 (base) + JS489 (lid)	(1) Semi-rigid dual channel scope (≥0.7mm ID x ≤500mm L and ≥1.1mm ID x ≤500mm L) AND one of the following: (4) Stainless steel lumens (≥ 5.5mm ID x ≤ 166mm L; ≥ 7mm ID x ≤ 105mm L; ≥ 7.0mm ID x ≤ 227mm L; ≥ 7.8mm ID x ≤ 198mm L) OR (2) Stainless steel lumens (≥ 4mm ID x ≤ 370mm L; ≥ 2mm ID x ≤ 152mm L) OR (3) Stainless steel lumens (≥ 2.2mm ID x ≤ 173mm L; ≥ 4.7mm ID x ≤ 270mmL ; ≥ 4mm ID x ≤ 445mm L)

Table 2. SterilContainer S2 System Load Weights

Sterilization Method	Container Size	Container Bottom Part #	Container Lid Part #	Total Loaded Container (lb)
EtO	Full Size - 4 ¼"	JS440	JS489	25
	Full Size - 5 ½"	JS441		
	Full Size - 6"	JS442		
	Full Size - 8"	JS444		
	Three-Quarter Size - 4 ¼"	JS740	JS789	25
	Three-Quarter Size - 5 ½"	JS741		
	Three-Quarter Size - 6"	JS742		
	Three-Quarter Size - 8"	JS744*		
	Half Size - 4 ½"	JS340	JS389	25
	Half Size - 5 ½	JS341		
	Half Size - 6"	JS342		
STERRAD 100NX DUO	Full Size - 4 ¼"	JS440	JS489	10.97
	Full Size - 5 ½"	JS441		
	Full Size - 6"	JS442		
	Full Size - 8"	JS444		
	Three-Quarter Size - 4 ¼"	JS740	JS789	10.04
	Three-Quarter Size - 5 ½"	JS741		
	Three-Quarter Size - 6"	JS742		
	Half Size - 4 ¼"	JS340	JS389	11.7
	Half Size - 5 ½	JS341		
	Half Size - 6"	JS342		
STERIZONE Validated Loads 1 & 2 (Based on Sterizone Load #7)	Full Size - 4 ¼"	JS440	JS489	25
	Full Size - 5 ½"	JS441		
	Full Size - 6"	JS442		
	Full Size - 8"	JS444		
	Three-Quarter Size - 4 ¼"	JS740	JS789	25
	Three-Quarter Size - 5 ½"	JS741		
	Three-Quarter Size - 6"	JS742		
	Half Size - 4 ¼"	JS340	JS389	25
	Half Size - 5 ½	JS341		
	Half Size - 6"	JS342		
	Half Size - 5 ½	JS341		
	Half Size - 6"	JS342		
STERIZONE Validated Load 3 (Based on Sterizone Load #8)	Full Size - 4 ¼"	JS440	JS489	See load configuration in table 1 above
STERIZONE Validated Load 4 (Based on Sterizone Load #4)	Full Size - 4 ¼"	JS440	JS489	See load configuration in table 1 above

*JS744 is for use in Ethylene Oxide only.

Table 3. Sterilization Cycle Compatible Accessories

Accessories	Compatible with Ethylene Oxide	Compatible with STERRAD DUO	Compatible with STERIZONE VP4
Stainless Steel baskets, basket lids, and dividers	Yes	Yes	Yes
Instrument Organization System (Silicone and Stainless Steel racks, brackets, holders, and clamps)	Yes	Yes	Yes
Silicone mats	Yes	No	Yes
Tamper Evident locks and indicator cards	Yes	Yes	Yes

TECHNOLIGICAL CHARACTERISTICS (compared to predicate devices)

The Aesculap SterilContainer S2 System has the same intended use and the technological characteristics as the Aesculap SterilContainer predicate devices. The subject devices are offered in the same design and same sizes and are made of the same materials as the predicate devices.

	Subject Device - Aesculap SterilContainer S2 (K193582)	**Primary Predicate – Aesculap SterilContainer S2 (K182414)**	**Predicate – Aesculap SterilContainer (K112671)**	**Predicate – Aesculap SterilContainer S (K162815)**	**Discussion**
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.	The subject device and the predicates have the same intended use.
Sterilization Modalities	EtO STERIZONE VP4 STERRAD 100NX DUO	Prevac Steam Gravity Steam STERRAD: 100S, NX Standard, NX Advanced, 100NX Standard, 100NX Flex 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	EtO PreVac Steam Gravity Steam IUSS	STERIZONE VP4	The subject device has been validated using sterilization methods similar to the predicate devices.
Material	Container: Anodized aluminum Lid: Anodized aluminum Gasket: Silicone	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	The material of the subject device is identical to the predicates.
Filter Type	Single use: Paper (cellulose) or polypropylene	Single use: Paper (cellulose) or polypropylene Reusable: PTFE	Single use: Paper (cellulose) or polypropylene Reusable: PTFE	Single use: polypropylene	The proposed device utilizes an identical single use filter.
Container Design	Perforated bottom with perforated lid	Perforated bottom with perforated lid	Perforated or solid bottom with perforated lid	Perforated bottom with perforated lid	The design of the subject device is identical to that of the predicate devices.
Vent to Volume ratio	1.02 – 3.4	1.4 – 3.4	1.02	1.4 – 3.4	The vent-to-volume ratios of the subject device fall within those of the predicates.
Sizes	Full size Three-Quarter Size Half Size	Full size Three-Quarter Size Half Size	Three-Quarter Size	Full size Three-Quarter Size Half Size	The size of the subject device and predicate devices are the same.
Accessories	Silicone mats, baskets, trays, IOS, and racks.	Silicone mats, baskets, trays, IOS, and racks.	Silicone mats, baskets, trays, IOS, and racks.	Silicone mats, baskets, trays, IOS and racks.	The subject and predicate devices utilize the same accessories.

PERFORMANCE TESTING

Non-clinical testing was conducted to verify performance of the subject device. The testing summarized below demonstrates that the subject device meets the established acceptance criteria.

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
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 demonstrate that the Aesculap SterilContainer S2 System is as safe, as effective, and performs as well as or better than the legally marketed predicate devices.