March 27, 2020

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

Re: K192056
Trade/Device Name: Aesculap JJ Series Container System
Regulation Number: 21 CFR 880.6850
Regulation Name: Sterilization Wrap
Regulatory Class: Class II
Product Code: KCT
Dated: February 25, 2020
Received: February 27, 2020

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)*
K192056

Device Name

Aesculap JJ Series Container System

Indications for Use *(Describe)*

The Aesculap JJ Series Container 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 during transport and until used. This container system is compatible for use in steam sterilization according to the configurations listed in the tables below.

The JJ Series Container System consists of two different container styles: a solid bottom container and enhanced drying system (EDS) container.

The Aesculap JJ Series Container System includes accessories such as baskets, trays, silicone mats, instrument organizational accessories, holders, indicator cards, tamper evident locks, lid covers, faceplate holders, and tags.

The attached tables identifies the load configurations.

Table 1. JJ Series Container System Lumen Configurations

Sterilization Cycle	Size	Lumens
PreVac Steam with dry time (270°F 4 min Exposure)	Full Size	4 stainless steel lumens with ≥ 1mm ID x ≤500mm L
	Three-Quarter	4 stainless steel lumens with ≥ 1mm ID x ≤400mm L
	Half Size	4 stainless steel lumens with ≥ 1mm ID x ≤200mm L
Prevac Steam without dry time (270°F 3 min Exposure) Non-Porous	Full Size	Non lumened instruments
	Three-Quarter Size	Non lumened instruments
	Half Size	Non lumened instruments
Prevac Steam without dry time (270°F 4 min Exposure) Porous	Full Size	4 stainless steel lumens with ≥ 1mm ID x ≤500mm L
	Three-Quarter Size	4 stainless steel lumens with ≥ 1mm ID x ≤400mm L
	Half Size	4 stainless steel lumens with ≥ 1mm ID x ≤125mm L

Validation testing was performed using the JJ612 single use paper filter.

Table 2. JJ Series Container System Configurations, Without Silicone Mat and Lid cover*

Container Type	Sterilization Method	Container Bottom Part #	Container Lid Part #	Maximum Load Weight (lbs)*
Solid Bottom Container	Prevac Steam 270°F 4 min exposure 15 minute* dry time	JJ140	JJ410	25
		JJ130		24
		JJ120		23
		JJ110		22
		JJ340	JJ430	23
		JJ330		22
		JJ320		20
		JJ310		18
		JJ240	JJ420	18
		JJ230		18
		JJ220		15
		JJ210		13
EDS Container	Prevac Steam 270°F 4 min exposure 8 minute* dry time	JJ141	JJ410	25
		JJ131		24
		JJ121		23
		JJ111		22
		JJ341	JJ430	23
		JJ331		22
		JJ321		20
		JJ311		18
		JJ241	JJ420	18
		JJ231		18
		JJ221		15
		JJ211		13
Solid Bottom Container	Prevac Steam Without dry time 270°F 3 min Exposure (Non-porous) AND Prevac Steam Without dry time 270°F 4 min Exposure (Porous)	JJ140	JJ410	25
		JJ130		
		JJ120		
		JJ110		
		JJ340	JJ430	25
		JJ330		
		JJ320		
		JJ310		
		JJ240	JJ420	25
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		JJ231		
		JJ221		
		JJ211		

Table 3. JJ Series Container System Configurations, with Silicone Mat and Lid Cover*

Container Type	Sterilization Method	Container Bottom Part #	Container Lid Part #	Maximum Load Weight (lbs)*
Solid Bottom Container	Prevac Steam 270°F 4 min exposure 30 minute* dry time	JJ140	JJ410	25
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		JJ341	JJ430	25
		JJ331		
		JJ321		
		JJ311		
		JJ241	JJ420	25
		JJ231		
		JJ221		
		JJ211		

*Dry times and load weights are based on container with silicone mats and/or lid cover.

Table 4: Sterilization Cycle Compatible Accessories - Prevac Steam

Accessories	Prevac Steam with dry time	Prevac Steam Without dry time
Baskets, trays, indicator cards, tamper evident locks, faceplate holders, and tags.	Yes	Yes
Instrument Organization System (Silicone and Stainless Steel racks, brackets, holders, and clamps)	Yes	Yes
Silicone mats	Yes[1]	Yes
Lid Covers	Yes[1]	Yes

[1] Using silicone mats and/or lid covers may require a longer drying time.

When used with PreVac Steam with dry time (270°F, 4 minute exposure), the maintenance of sterility of the Aesculap JJ Series Container System is 365 days.

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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5. 510(k) SUMMARY (as required by 21 CFR 807.92)

Aesculap JJ Series Container System for Steam
March 27, 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® JJ Series Container 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

DEVICE DESCRIPTION

The Aesculap JJ Series Container 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 Prevac steam with and without dry time.

The JJ Series Container System consists of two different container styles: a solid bottom container and enhanced drying system (EDS) container.

The containers are made from anodized aluminum and utilize a single-use filter. The JJ Series Container System includes accessories such as baskets, trays, silicone mats, instrument organizational accessories, holders, indicator cards, tamper evident locks, lid covers, faceplate holders, and tags.

INDICATIONS FOR USE

The Aesculap JJ Series Container 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 during transport and until used. This container system is compatible for use in steam sterilization according to the configurations listed in the tables below.

The JJ Series Container System consists of two different container styles: a solid bottom container and enhanced drying system (EDS) container.

The Aesculap JJ Series Container System includes accessories such as baskets, trays, silicone mats, instrument organizational accessories, holders, indicator cards, tamper evident locks, lid covers, faceplate holders, and tags.

The attached tables identifies the load configurations.

Table 1. JJ Series Container System Lumen Configurations

Sterilization Cycle	Size	Lumens
PreVac Steam with dry time (270°F 4 min Exposure)	Full Size	4 stainless steel lumens with ≥ 1mm ID x ≤500mm L
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Prevac Steam without dry time (270°F 3 min Exposure) Non-Porous	Full Size	Non lumened instruments
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	Half Size	Non lumened instruments
Prevac Steam without dry time (270°F 4 min Exposure) Porous	Full Size	4 stainless steel lumens with ≥ 1mm ID x ≤500mm L
	Three-Quarter Size	4 stainless steel lumens with ≥ 1mm ID x ≤400mm L
	Half Size	4 stainless steel lumens with ≥ 1mm ID x ≤125mm L

Validation testing was performed using the JJ612 single use paper filter.

Table 2. JJ Series Container System Configurations, Without Silicone Mat and Lid cover*

Container Type	Sterilization Method	Container Bottom Part #	Container Lid Part #	Maximum LoadWeight (lbs)*
Solid Bottom Container	Prevac Steam 270°F 4 min exposure 15 minute* dry time	JJ140	JJ410	25
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		JJ120		23
		JJ110		22
		JJ340	JJ430	23
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		JJ320		20
		JJ310		18
		JJ240	JJ420	18
		JJ230		18
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		JJ131		24
		JJ121		23
		JJ111		22
		JJ341	JJ430	23
		JJ331		22
		JJ321		20
		JJ311		18
		JJ241	JJ420	18
		JJ231		18
		JJ221		15
		JJ211		13
Solid Bottom Container	Prevac Steam Without dry time 270°F 3 min Exposure (Non-porous) AND Prevac Steam Without dry time 270°F 4 min Exposure (Porous)	JJ140	JJ410	25
		JJ130		
		JJ120		
		JJ110		
		JJ340	JJ430	25
		JJ330		
		JJ320		
		JJ310		
		JJ240	JJ420	25
		JJ230		
		JJ220		
		JJ210		
EDS Container	Prevac Steam Without dry time 270°F 3 min Exposure (Non-porous) AND Prevac Steam Without dry time	JJ141	JJ430	25
		JJ131		
		JJ121		
		JJ111		
		JJ341	JJ310	25
		JJ331		
		JJ321		
		JJ311		

	270°F 4 min Exposure (Porous)	JJ241	JJ420	25
		JJ231		
		JJ221		
		JJ211		

Table 3. JJ Series Container System Configurations, with Silicone Mat and Lid Cover*

Container Type	Sterilization Method	Container Bottom Part #	Container Lid Part #	Maximum Load Weight (lbs)*
Solid Bottom Container	Prevac Steam 270°F 4 min exposure 30 minute* dry time	JJ140	JJ410	25
		JJ130		24
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		JJ341	JJ430	25
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		JJ241	JJ420	25
		JJ231		
		JJ221		
		JJ211		

*Dry times and load weights are based on container with silicone mats and/or lid cover.

Table 4: Sterilization Cycle Compatible Accessories - Prevac Steam

Accessories	Prevac Steam with dry time	Prevac Steam Without dry time
Baskets, trays, indicator cards, tamper evident locks, faceplate holders, and tags.	Yes	Yes
Instrument Organization System (Silicone and Stainless Steel racks, brackets, holders, and clamps)	Yes	Yes
Silicone mats	Yes[1]	Yes
Lid Covers	Yes[1]	Yes

[1] Using silicone mats and/or lid covers may require a longer drying time.

When used with PreVac Steam with dry time (270◦F, 4 minute exposure), the maintenance of sterility of the Aesculap JJ Series Container System is 365 days.

TECHNOLIGICAL CHARACTERISTICS (compared to predicate device)

The Aesculap JJ Series Container System has the same intended use as the Aesculap predicate device. The subject device is offered in similar sizes and is comprised of similar materials of construction as the predicate device.

	Subject Device - Aesculap JJ Series Container System (K192056) Product Code: KCT	**Predicate Device– Aesculap SterilContainer (K112671) Product Code: KCT**	
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.	Same
Sterilization Modalities	PreVac Steam with dry time PreVac Steam without dry time	PreVac Steam IUSS Ethylene Oxide	Similar
Material	Container: Anodized aluminum Lid: Anodized aluminum Gasket: Silicone	Container: Anodized aluminum Lid: Anodized aluminum Gasket: Silicone	Same
Filter Type	Single use (Paper)	Single use (Paper) and reusable (PTFE)	Similar
Container Design	Solid bottom or Solid bottom with enhanced drying system Perforated Lid	Solid or perforated bottom Perforated lid	Similar
Sizes	Full size Three-Quarter Size Half Size	Three-Quarter Size	Similar
Accessories	Baskets, trays, silicone mats, instrument organizational accessories, holders, indicator cards, tamper evident locks, lid covers, faceplate holders, and tags.	Silicone mats, instrument organization system, lid covers, baskets, trays, and racks, indicator cards, locks	Similar
Maintenance of Sterility	Prevac Steam with dry time – 365 days	Prevac Steam & Ethylene Oxide– 360 days IUSS – N/A	Similar

SUMMARY OF NONCLINICAL PERFORMANCE DATA

The Aesculap JJ Series Container 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:

- Prevac steam with dry time (Exposure: 270°F for 4 minutes)
- Prevac steam without dry time (Exposure: 270°F for 4 minutes – Porous)
- Prevac steam without dry time (Exposure: 270°F for 3 minutes – Non-Porous)

Testing was conducted in accordance with applicable FDA guidance and standards. The table below outlines the testing which was performed on the subject device.

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 indicated in section 5.6 of AAMI ST-77. Biological indicators must be negative for growth after incubation period.	Pass
Dry Time	To determine the proper drying time required for the JJ Series Container System.	Per AAMI ST-77 section 4.4.2, (in association with EN 868-8 section G.3/G.4 and EN 285 section G20.3), the system shall demonstrate an average pre and post sterilization weight difference of less than 0.2% within five 5 minutes of cycle completion using final validated parameters and be free of visible moisture following a cooling period.	Pass
Microbial Aerosol Challenge	To analyze the package integrity and microbial barrier properties of the test device.	The container load maintains sterility after exposure to a defined amount of aerosol microorganisms per ST-77 sections 5.9.1.1 & 5.9.1.2. No presence of growth after incubation period.	Pass
Sterility Maintenance	To demonstrate that a processed test device can maintain a sterile barrier for a defined period of time.	Sterility of container contents is maintained under conditions which simulate hospital sterile package handling and storage conditions and were tested per ISO 11167-1 section 6.4. Test articles stored for their post processing shelf life. 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 according to section 5.0 of TIR17.	Pass
Cytotoxicity	To determine the potential of a test device to cause cytotoxicity.	Testing completed in accordance with ISO 10993-5:2009. Using the ISO Elution Method, the response to the article must not be greater than 2 (mild reactivity).	Pass
Cleaning Validation	To verify the effectiveness of the device cleaning procedure.	In accordance with Annex A and section 7.5 of TIR30, test samples shall show no visible soil after cleaning and shall have protein or hemoglobin levels less than the predetermined amounts.	Pass

Results of the testing demonstrate that the proposed device met the acceptance criteria for each performance test.

CONCLUSION

The conclusions drawn from the nonclinical tests demonstrate that Aesculap JJ Series Container System the device is as safe, as effective, and performs as well as or better than the legally marketed device.