



November 16, 2018

Summit Medical Inc.
Nicole Dove
Director of Quality Assurance and Regulatory Affairs
815 Northwest Parkway, Suite 100
St. Paul, Minnesota 55121

Re: K180528
Trade/Device Name: InstruSafe® Sterilization Container
Regulation Number: 21 CFR 880.6850
Regulation Name: Sterilization Wrap
Regulatory Class: Class II
Product Code: KCT
Dated: October 16, 2018
Received: October 17, 2018

Dear Nicole Dove:

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,

Clarence W. Murray III -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

510(k) Number (if known)
K180528

Device Name
IntruSafe® Sterilization Container

Indications for Use (Describe)

The IntruSafe® Sterilization Container 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 for 180 days. The IntruSafe® Sterilization Container includes accessories such as trays, baskets, filters, data cards and tamper proof locks.

The IntruSafe® Sterilization Container consists of various models within the validated product line. All models are available with perforated lids and either perforated or non-perforated bottoms. All models are intended to be used with single use paper filters.

The container is a reusable device designed to be used with the following sterilization cycle parameters:

Pre-Vacuum Steam Sterilization Cycle:

4 minutes

132oC (270 oF)

Drying Time Minimum: 30 minutes

Model Number	Description	Total Container Loaded Maximum Weight (lbs)	Load Description
CS-3XXX	Full 1/1 Perforated Container Lid	Not applicable	Metal (Stainless Steel) surgical instruments like forceps, scissors, clamps, etc. including lumened /cannulated instruments.
CS-3XXX	Full 1/1 Container Bottom	25 lbs	
CS-2XXX	Three quarter ¾ Perforated Container Lid	Not applicable	
CS-2XXX	Three quarter ¾ Container Bottom	25 lbs	
CS-1XXX	One half ½ Perforated Container Lid	Not applicable	
CS-1XXX	One half ½ Container Bottom	18 lbs	
CS-5XXX	XL Perforated Container Lid	Not applicable	
CS-5XXX	XL Container Bottom	25 lbs	

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
K180528

Following is the 510(k) summary information in accordance with 21 CFR 807.92

Date Prepared:	October 15, 2018
Applicant:	Summit Medical, Inc. 815 Vikings Parkway, Suite 100 St. Paul, MN 55121 USA
Official Correspondent:	Nicole Dove Director of Quality Assurance & Regulatory Affairs Tel: (651) 789-3921 / Fax: (651) 789-3961 ndove@innoviamedical.com
	Subject Device
Trade/Device Name:	InstruSafe® Sterilization Container
Common or Usual Name:	Instrument Tray, Sterilization Tray, Sterilization Cassettes, Instrument Delivery System
Regulation Number:	21 CFR 880.6850
Regulation Name:	Sterilization wrap
Regulatory Class:	Class II
Product Code:	KCT
Indications for Use	The InstruSafe® Sterilization Container 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 for 180 days. The InstruSafe® Sterilization Container includes accessories such as trays, baskets, filters, data cards and tamper proof locks. The InstruSafe® Sterilization Container consists of various models within the validated product line. All models are available with perforated lids and either perforated or non-perforated bottoms. All models are intended to be used with single use paper filter. The container is a reusable device designed to be used with the following sterilization cycle parameters: <u>Pre-Vacuum Steam Sterilization Cycle:</u> 4 minutes 132°C (270 °F) Drying Time Minimum: 30 minutes



	Model Number	Description	Total Container Loaded Maximum Weight (lbs)	Load Description																																																																																								
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Device Description	The InstruSafe® Sterilization Container is a reusable sterilization container system intended to be used to enclose another medical device that is to be sterilized by a healthcare provider. They consist of various sizes of bottoms and lids that provide an effective packaging method for sterilization, storage and transportation of surgical instruments by healthcare providers. These containers are suitable for use in pre-vacuum Steam Sterilizers with a tray or basket accessory. Metal (Stainless Steel) surgical instruments like forceps, scissors, clamps, etc. including lumenated/cannulated instruments are placed in the trays or baskets for sterilization. Note: The maximum number of Lumens/Lumen Configuration is as follow: 2 lumens with ≥ 1mm I.D. x ≤ 200mm and a second lumen ≥ 5mm I.D. x ≤ 400mm The containers are available in different models such as full size (1/1), three-quarter size (3/4), half size (1/2) and XL. InstruSafe® Sterilization Container is manufactured using aluminum alloy, stainless steel, silicone and the surfaces are protected by a layer of anodized aluminum oxide to prevent corrosion. The containers must only be used with single use paper filters. <u>Maximum recommended loading:</u> <table><tr><th>Model Number</th><th>Description</th><th>Standard Dimension Outside w/cover LxWxH in inches</th><th>Total Container Loaded Maximum Weight (lbs)</th></tr><tr><td>CS-3001</td><td>Full 1/1 Perforated Container Lid</td><td>23 1/8 x 11 x 1 ¼</td><td>Not applicable</td></tr><tr><td>CS-3002</td><td>Full 1/1 Solid Container Bottom</td><td>23 1/8 x 11 x 4 1/4</td><td>25 lbs</td></tr><tr><td>CS-3003</td><td>Full 1/1 Solid Container Bottom</td><td>23 1/8 x 11 x 6 ¼</td><td>25 lbs</td></tr><tr><td>CS-3004</td><td>Full 1/1 Solid Container Bottom</td><td>23 1/8 x 11 x 8 ¼</td><td>25 lbs</td></tr><tr><td>CS-3005</td><td>Full 1/1 Solid Container Bottom</td><td>23 1/8 x 11x 10 ½</td><td>25 lbs</td></tr><tr><td>CS-3012</td><td>Full 1/1 Perforated Container Bottom</td><td>23 1/8 x 11 x 4 ¼</td><td>25 lbs</td></tr><tr><td>CS-3013</td><td>Full 1/1 Perforated Container Bottom</td><td>23 1/8 x 11 x 6 ¼</td><td>25 lbs</td></tr><tr><td>CS-3014</td><td>Full 1/1 Perforated Container Bottom</td><td>23 1/8 x 11 x 8 ¼</td><td>25 lbs</td></tr><tr><td>CS-3015</td><td>Full 1/1 Perforated Container Bottom</td><td>23 1/8 x 11x 10 ½</td><td>25 lbs</td></tr><tr><td>CS-2001</td><td>Three Quarter ¾ Perforated Container Lid</td><td>18 ¼ x 11 x 1 ¼</td><td>Not applicable</td></tr><tr><td>CS-2002</td><td>Three Quarter ¾ Solid Container Bottom</td><td>18 ¼ x 11 x 4 ¼</td><td>25 lbs</td></tr><tr><td>CS-2003</td><td>Three Quarter ¾ Solid Container Bottom</td><td>18 ¼ x 11 x 6 ¼</td><td>25 lbs</td></tr><tr><td>CS-2012</td><td>Three Quarter ¾ Perforated Container Bottom</td><td>18 ¼ x 11 x 4 ¼</td><td>25 lbs</td></tr><tr><td>CS-2013</td><td>Three Quarter ¾ Perforated Container Bottom</td><td>18 ¼ x 11 x 6 ¼</td><td>25 lbs</td></tr><tr><td>CS-1001</td><td>One Half ½ Perforated Container Lid</td><td>11 ½ x 11 x 1 ¼</td><td>Not applicable</td></tr><tr><td>CS-1002</td><td>One Half ½ Solid Container Bottom</td><td>11 ½ x 11 x 4 ¼</td><td>18 lbs</td></tr><tr><td>CS-1003</td><td>One Half ½ Solid Container Bottom</td><td>11 ½ x 11 x 6 ¼</td><td>18 lbs</td></tr><tr><td>CS-1012</td><td>One Half ½ Perforated Container Bottom</td><td>11 ½ x 11 x 4 ¼</td><td>18 lbs</td></tr><tr><td>CS-1013</td><td>One Half ½ Perforated Container Bottom</td><td>11 ½ x 11 x 6 ¼</td><td>18 lbs</td></tr><tr><td>CS-5000</td><td>Extra Large Perforated Container Lid</td><td>30 7/8 x 12 ¾ x 7 ½</td><td>Not applicable</td></tr><tr><td>CS-5001</td><td>Extra Large Perforated Container Bottom</td><td>30 7/8 x 12 ¾ x 7 ½</td><td>25 lbs</td></tr></table>				Model Number	Description	Standard Dimension Outside w/cover LxWxH in inches	Total Container Loaded Maximum Weight (lbs)	CS-3001	Full 1/1 Perforated Container Lid	23 1/8 x 11 x 1 ¼	Not applicable	CS-3002	Full 1/1 Solid Container Bottom	23 1/8 x 11 x 4 1/4	25 lbs	CS-3003	Full 1/1 Solid Container Bottom	23 1/8 x 11 x 6 ¼	25 lbs	CS-3004	Full 1/1 Solid Container Bottom	23 1/8 x 11 x 8 ¼	25 lbs	CS-3005	Full 1/1 Solid Container Bottom	23 1/8 x 11x 10 ½	25 lbs	CS-3012	Full 1/1 Perforated Container Bottom	23 1/8 x 11 x 4 ¼	25 lbs	CS-3013	Full 1/1 Perforated Container Bottom	23 1/8 x 11 x 6 ¼	25 lbs	CS-3014	Full 1/1 Perforated Container Bottom	23 1/8 x 11 x 8 ¼	25 lbs	CS-3015	Full 1/1 Perforated Container Bottom	23 1/8 x 11x 10 ½	25 lbs	CS-2001	Three Quarter ¾ Perforated Container Lid	18 ¼ x 11 x 1 ¼	Not applicable	CS-2002	Three Quarter ¾ Solid Container Bottom	18 ¼ x 11 x 4 ¼	25 lbs	CS-2003	Three Quarter ¾ Solid Container Bottom	18 ¼ x 11 x 6 ¼	25 lbs	CS-2012	Three Quarter ¾ Perforated Container Bottom	18 ¼ x 11 x 4 ¼	25 lbs	CS-2013	Three Quarter ¾ Perforated Container Bottom	18 ¼ x 11 x 6 ¼	25 lbs	CS-1001	One Half ½ Perforated Container Lid	11 ½ x 11 x 1 ¼	Not applicable	CS-1002	One Half ½ Solid Container Bottom	11 ½ x 11 x 4 ¼	18 lbs	CS-1003	One Half ½ Solid Container Bottom	11 ½ x 11 x 6 ¼	18 lbs	CS-1012	One Half ½ Perforated Container Bottom	11 ½ x 11 x 4 ¼	18 lbs	CS-1013	One Half ½ Perforated Container Bottom	11 ½ x 11 x 6 ¼	18 lbs	CS-5000	Extra Large Perforated Container Lid	30 7/8 x 12 ¾ x 7 ½	Not applicable	CS-5001	Extra Large Perforated Container Bottom	30 7/8 x 12 ¾ x 7 ½	25 lbs
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Predicate Device	
Trade/Device Name/510(k)	Ermis Medizintechnik Sterilization Container System - K123234
Reference Device	
Trade/Device Name/510(k)	Aesculap SterilContainer System – K112671 (reference)

Comparison of Subject Device to Predicate Devices																														
Indications for Use	InstruSafe® Sterilization Container The InstruSafe® Sterilization Container 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 for 180 days. The InstruSafe® Sterilization Container includes accessories such as trays, baskets, filters, data cards and tamper proof locks. The InstruSafe® Sterilization Container consists of various models within the validated product line. All models are available with perforated lids and either perforated or non-perforated bottoms. All models are intended to be used with single use paper filter. The container is a reusable device designed to be used with the following sterilization cycle parameters: <u>Pre-Vacuum Steam Sterilization Cycle:</u> 4 minutes 132°C (270 °F) Drying Time Minimum: 30 minutes <table><tr><th>Model Number</th><th>Description</th><th>Total Container Loaded Maximum Weight (lbs)</th><th>Load Description</th></tr><tr><td>CS-3XXX</td><td>Full 1/1 Perforated Container Lid</td><td>Not applicable</td><td rowspan="8">Metal (Stainless Steel) surgical instruments like forceps, scissors, clamps, etc. including lumened /cannulated instruments.</td></tr><tr><td>CS-3XXX</td><td>Full 1/1 Container Bottom</td><td>25 lbs</td></tr><tr><td>CS-2XXX</td><td>Three quarter ¾ Perforated Container Lid</td><td>Not applicable</td></tr><tr><td>CS-2XXX</td><td>Three quarter ¾ Container Bottom</td><td>25 lbs</td></tr><tr><td>CS-1XXX</td><td>One half ½ Perforated Container Lid</td><td>Not applicable</td></tr><tr><td>CS-1XXX</td><td>One half ½ Container Bottom</td><td>18 lbs</td></tr><tr><td>CS-5XXX</td><td>XL Perforated Container Lid</td><td>Not applicable</td></tr><tr><td>CS-5XXX</td><td>XL Container Bottom</td><td>25 lbs</td></tr></table>	Model Number	Description	Total Container Loaded Maximum Weight (lbs)	Load Description	CS-3XXX	Full 1/1 Perforated Container Lid	Not applicable	Metal (Stainless Steel) surgical instruments like forceps, scissors, clamps, etc. including lumened /cannulated instruments.	CS-3XXX	Full 1/1 Container Bottom	25 lbs	CS-2XXX	Three quarter ¾ Perforated Container Lid	Not applicable	CS-2XXX	Three quarter ¾ Container Bottom	25 lbs	CS-1XXX	One half ½ Perforated Container Lid	Not applicable	CS-1XXX	One half ½ Container Bottom	18 lbs	CS-5XXX	XL Perforated Container Lid	Not applicable	CS-5XXX	XL Container Bottom	25 lbs
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Reference Device Aesculap SterilContainer System K112671 The Aesculap SterilContainer System 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 for 360 days. The SterilContainer System includes accessories such as mats, baskets, trays, holders, organizers, filters, indicator cards and tamper proof locks.																														

		The container system consists of a three-quarter size, 8” tall perforated (JN744) or solid (JK744) aluminum bottom and a three-quarter size aluminum or PrimeLine lid. The lids are available in different colors to aide in set recognition. There are three types of filter materials. A single use paper filter (US751, US994), a single use polypropylene filter (MD344) and a reusable PTFE filter (JK090). The reusable PTFE is validated for 2200 uses. There are a variety of accessories for use with the container system. Please refer to the chart on the next page for sterilization compatibility of the container system.																																													
	Predicate Device: Ermis Medizintechnik Sterilization Container System K123234	The ERMIS Sterilization Container System is intended to allow sterilization of the enclosed medical device and also maintain sterility during transport and storage for 30 days. The system consists of different models, such as 1/1 Size,¾ Size,½ size, mini and dental containers which may vary in size, perforations and color. All models are available with perforated lids and either perforated or non-perforated bottoms. To enable proper organization of sterilized goods, different wire- or sleeve baskets exactly adapted to the specific container dimensions are available. All models are intended to be used with Ermis single use paper filters. The containers are reusable devices designed to be used with the following sterilization cycle parameters: <u>Pre-Vacuum cycle:</u> 4minutes 132°C (270°F) Drying Time minimum 20 minutes 3minutes 135°C (273°F) Drying Time minimum 16 minutes Loading: Metal surgical instruments (scissors, clamps, forceps) and textiles <u>Maximum recommended loading:</u> <table><tr><th rowspan="2">Model</th><th rowspan="2">Dimension</th><th colspan="2">Maximum Recommended Load in kg (lbs.) incl. Container weight</th></tr><tr><th>Instruments</th><th>Textiles</th></tr><tr><td rowspan="5">1/1 Size Container</td><td>580x280x100</td><td>3.8 (8.3)</td><td>3 (6.6)</td></tr><tr><td>580x280x135</td><td>5.2 (11.4)</td><td>4.1 (9.0)</td></tr><tr><td>580x280x150</td><td>5.8 (12.7)</td><td>4.6 (10.1)</td></tr><tr><td>580x280x200</td><td>7.7 (16.9)</td><td>6.1 (13.4)</td></tr><tr><td>580x280x260</td><td>10 (22.0)</td><td>8 (17.6)</td></tr><tr><td rowspan="3">¾ Size Container</td><td>465x280x100</td><td>3.1 (6.8)</td><td>2.5 (5.5)</td></tr><tr><td>465x280x135</td><td>4.2 (9.2)</td><td>3.3 (7.2)</td></tr><tr><td>465x280x150</td><td>4.6 (10.1)</td><td>3.7 (8.1)</td></tr><tr><td rowspan="3">½ Size Container</td><td>285x280x100</td><td>1.9 (4.1)</td><td>1.5 (3.3)</td></tr><tr><td>285x280x135</td><td>2.6 (5.7)</td><td>2 (4.4)</td></tr><tr><td>285x280x150</td><td>2.8 (6.1)</td><td>2.2 (4.8)</td></tr></table>				Model	Dimension	Maximum Recommended Load in kg (lbs.) incl. Container weight		Instruments	Textiles	1/1 Size Container	580x280x100	3.8 (8.3)	3 (6.6)	580x280x135	5.2 (11.4)	4.1 (9.0)	580x280x150	5.8 (12.7)	4.6 (10.1)	580x280x200	7.7 (16.9)	6.1 (13.4)	580x280x260	10 (22.0)	8 (17.6)	¾ Size Container	465x280x100	3.1 (6.8)	2.5 (5.5)	465x280x135	4.2 (9.2)	3.3 (7.2)	465x280x150	4.6 (10.1)	3.7 (8.1)	½ Size Container	285x280x100	1.9 (4.1)	1.5 (3.3)	285x280x135	2.6 (5.7)	2 (4.4)	285x280x150	2.8 (6.1)	2.2 (4.8)
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			Mini Container	285x280x200	3.8 (8.3)	3 (6.6)	
				285x280x260	4.9 (10.8)	3.9 (8.5)	
				300x140x40	0.4 (0.8)	0.3 (0.6)	
				300x140x70	0.7 (1.5)	0.5(1.1)	
				300x140x100	1 (2.2)	0.8 (1.7)	
			Dental Container	310x190x40	0.6(1.3)	0.5(1.1)	
				310x190x65	0.9 (1.9)	0.7 (1.5)	
				310x190x80	1.2 (2.6)	0.9 (1.9)	
				310x190x100	1.5 (3.3)	1.2 (2.6)	
				310x190x130	1.8 (3.9)	1.4 (3.0)	

Technological Characteristics/Performance Comparison of Subject Device to Predicate Device	InstruSafe® Sterilization Container (K180528)	Reference Device: Aesculap SterilContainer System K112671	Predicate Device: Ermis Medizintechnik Sterilization Container K123234
Materials	Anodized Aluminum Alloy, Stainless Steel, Silicone	Anodized Aluminum Alloy/Radel R	Anodized Aluminum Alloy, Stainless Steel, Silicone
Properties - Instruments to be sterilized in vacuum steam sterilizers - Reusable - Closed System - Sealed - Filtered to Permit Entry of Sterilant - Filtered to Prevent Microbial Migration during Transport - Incorporates security lid to prevent damage/contamination of filter unit during transport	Yes Yes No	Yes Yes No	Yes Yes Yes Yes Yes Yes Yes
Performance - Load Weight - Lumened/ cannulated instruments - Stainless steel medical devices	Up to 25 lbs Yes Yes	Up to 25 lbs Yes Yes	Up to 22 lbs No Yes



- Shelf life - Biocompatibility	180 Days meets requirements of ISO 10993-1	360 Days meets requirements of ISO 10993-1	90 Days meets requirements of ISO 10993-1
Discussion on Technological / Performance Characteristic Differences	There are four technological/performance characteristic differences between the predicate devices and the subject device (Reference Table above). These are: 1) Incorporates security lid to prevent damage/contamination of filter unit during transport, 2) Load weight 3) Lumened/cannulated instruments 4) Shelf life Scientific methods (bench testing) and sterilization standards, exist for evaluating different technical characteristics. Specifically: 1) Incorporates security lid to prevent damage/contamination of filter unit during transport a. The sterilization containers were tested without a security lid during sterilization efficacy, dry time, microbial aerosol challenge and shelf life testing and were found to have no failures that were caused by damage or contamination of the filter unit. The subject device functions as intended. 2) Load weight a. The sterilization containers were tested to the load weight claimed in the indications for use in the sterilization efficacy and dry time testing. The subject device functions as intended 3) Lumened/Cannulated instruments a. The sterilization containers were tested with lumened/cannulated instruments during sterilization efficacy testing. 4) Shelf life a. The sterilization containers were tested to the shelf life claimed in the indications for use during the sterilization efficacy testing.		
Non-Clinical Testing	The InstruSafe® Sterilization Container proved to be successful in all the non-clinical tests conducted. The non-clinical tests conducted included the tests listed below:	The Aesculap SterilContainer System conducted the following non-clinical tests: - Reprocessing Validation & Verification	The Ermis Sterilization Container System conducted the following non-clinical tests: - Pre-Vacuum Steam Efficacy



	- Pre-Vacuum Steam Efficacy and Thermal Profile - Dry Time - Maintenance of sterility (180 days) - Microbial Aerosol Challenge - Biocompatibility - Cleaning/reusability (AAMI TIR12) - Handle Testing - Gasket Testing - Lid/Base Compatibility Testing - Locking Tag/Label Compatibility Testing	- Sterilization Efficacy - Sterility Maintenance	- and Thermal Profile - Dry Time - Shelf Life - Microbial Aerosol Challenge - Biocompatibility - Mechanical Cleaning - Reusability (repetitive exposure) - Handle Testing - Lock Testing
Non-Clinical Testing Summary	The following Non-Clinical Testing was conducted using current standards and FDA guidance. - Pre-Vacuum Steam Efficacy and Thermal Profile, and Dry Time per AAMI TIR12:2010, ANSI/AAMI ST77:2013 and ANSI/AAMI ST79:2013/A4:2013 - Shelf Life and Microbial Aerosol Challenge per AAMI TIR12:2010, ANSI/AAMI ST77:2013 and ANSI/AAMI ST79:2010/A3:2012 - Biocompatibility per FDA Use of International Standard ISO 10993-1, “Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process”, ANSI/AAMI/ISO 10993-5:2009 and ANSI/AAMI/ISO 10993-12:2012 - Mechanical Cleaning per AAMI TIR12:2010, AAMI TIR30:2011 and ANSI/AAMI ST81:2004(R)2010 - Handle Testing, Gasket Testing, Lid/Base Compatibility Testing and Locking Tag/Label Compatibility Testing per ANSI/AAMI ST77:2013		
Conclusion:	In summary, the non-clinical testing demonstrates that the InstruSafe® Sterilization Container is as safe, as effective and performs as well as or better than the legally marketed predicate device (Ermis Medizintechnik Sterilization Container System K123234).		