May 1, 2025

Innovative Sterilization Technologies
℅ Joseph Azary
Regulatory Consultant
Aztech Regulatory & Quality LLC
543 Long Hill Avenue
Shelton, Connecticut 06484

Re: K250029
Trade/Device Name: ONE TRAY® Sealed Sterilization Container System
Regulation Number: 21 CFR 880.6850
Regulation Name: Sterilization Wrap
Regulatory Class: Class II
Product Code: KCT
Dated: April 1, 2025
Received: April 1, 2025

Dear Joseph Azary:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

Christopher K. Dugard -S

Christopher K. Dugard, M.S.
Director
DHT4C: Division of Infection Control 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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K250029

Device Name
ONE TRAY® Sealed Sterilization Container System

Indications for Use *(Describe)*
The ONE TRAY Container is a reusable rigid sterilization container intended to be used to enclose reusable medical devices that are to be steam sterilized by a healthcare provider. It is intended to allow sterilization of the enclosed devices and maintenance of sterility of 1he enclosed devices during storage, transport and until used. This container is compatible for use in the following sterilization modalities in the configuration listed below:

Prevac Steam
270°F, 4 min exposure
15 minute dry time

ONE TRAY® is validated to process a twenty five pound (25 lb) gross weight load (single container plus contents). This includes sterilization of lumens (Stainless Steel and Titanium) 1 mm in diameter or larger with lengths of up to 500 mm.

DO NOT STACK ONE TRAY CONTAINERS DURING STERILIZATION.

Examples of validated materials that can be processed within the ONE TRAY - Metals: S1ainless Steel, Titanium, Aluminum, Thermoplastics: PEEK, Polypropylene, Radel, Thermosetting Polymers: Silicone, Phenolic.

The ONE TRAY® sealed sterilization container consists of a line of rigid reusable containers listed in the table below. Healthcare Facilities should follow steam sterilization cycle and storage guidelines as stated in AAMI ST79, Comprehensive guide to steam sterilization and sterility assurance in health care facilities.

Catalog#	Length (in)	Width (in)	Height (in)
M2104DT	20.142	11.616	4.573
M2106DT	20.142	11.616	6.573
M2108DT	20.142	11.616	8.573
M2404DT	23.142	11.616	4.573
M2406DT	23.142	11.616	6.573
M2408DT	23.142	11.616	8.573

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

1. SUBMITTER/510(K) HOLDER

Innovative Sterilization Technologies, LLC
7625 Paragon Road, Suite A
Dayton, OH 45459

Contact Name: Walt Oko / Executive
Email: woko@ISTsterilization.com
Telephone: (937) 619-0138

Date: April 16, 2025

Prepared By: Joseph Azary / Aztech Regulatory & Quality LLC

2. DEVICE NAME

Proprietary Name:	ONE TRAY® Sealed Sterilization Container
Common/Usual Name:	Sterilization Container
Classification Name:	Sterilization Wrap Containers, Trays, Cassettes and other Accessories
Classification Regulation:	21 CFR 880.6850
Product code:	KCT
Classification:	Class 2
Medical Specialty (Panel):	Infection Control Devices Branch

3. PREDICATE DEVICES

- Predicate Device - Aesculap AICON Container – K214041
- Reference Device - IST ONE TRAY® sealed sterilization container – K052567

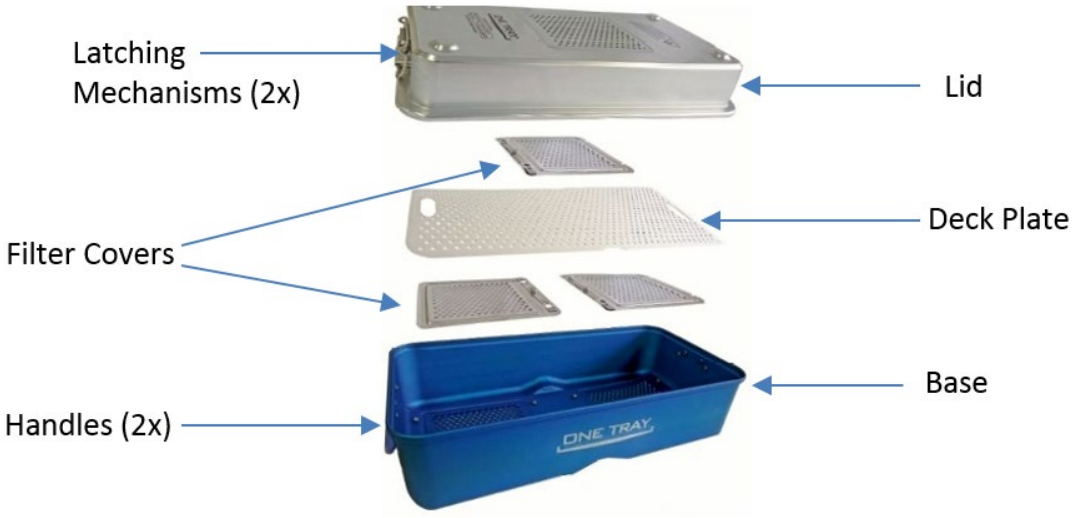
4. DEVICE DESCRIPTION

The ONE TRAY® Sealed Sterilization Container is a sealed rigid container with a lid and base containing a rectangular patterned group of perforations to permit steam penetration of sterilant.

Single use SMS filters cover each vented area and are held firmly in place by a perforated stainless steel filter cover. This assembly permits the penetration of steam during the sterilization process and serves as a bacterial and fluid barrier at the conclusion of the sterilization cycle.

ONE TRAY® Sealed Sterilization Containers are a reusable device whose base and lid are composed of anodized aluminum to prevent corrosion.

The gaskets used in the ONE TRAY® Sealed Sterilization Containers are made from medical grade silicone material identical to that used by predicate containers. The lid is firmly secured to the base with a cam-locking latch at each end.



Specifications and Configurations

The ONE TRAY® sealed sterilization container consists of a line of rigid reusable containers in various sizes. Innovative Sterilization Technologies intends to produce the following products:

Model	Model Description
M2104DT	(L) 20.142" x (H) 4.573" x (W) 11.616"
M2106DT	(L) 20.142" x (H) 6.573" x (W) 11.616"
M2108DT	(L) 20.142" x (H) 8.573" x (W) 11.616"
M2404DT	(L) 23.142" x (H) 4.573"x(W)11.616"
M2406DT	(L) 23.142" x (H) 6.573"x(W)11.616"
M2408DT	(L) 23.142" x (H) 8.573" x (W) 11.616"

Vent to Volume Ratios

The ONE TRAY® Sealed Sterilization Containers include filter vents in both the lid and base with covers for each filter element. These characteristics are common in other sterilization containers. The filtered vents in ONE TRAY® Sealed Sterilization Containers take advantage of the thermodynamic performance of a heated sterilizing media to facilitate the expeditious and complete introduction of the sterilant throughout the container.

The ONE TRAY® Sealed Sterilization Containers have one centrally located rectangular vent in the lid. The perforated area in this vent comprises approximately 30% of the surface area in the lid. Two vents of identical size and shape are laterally displaced and proximal to each end wall in the floor of the container. As steam is introduced through the dedicated entry vent in the lid of the ONE TRAY® Sealed Sterilization Container, the heated sterilant moves laterally to displace the relatively cooler atmosphere at the top of the container. As this process continues, the sterilant displaces the atmosphere within the container proceeding from the top to the bottom.

The location of the two vents in the floor force the steam to exit at the lateral extremes, which assist in reducing the presence of the usual “cool” spots in the bottom corners. This process occurs quickly due to the two vents having twice the surface area and vapor exchange capacity of the single vent in the lid. See Figure 1. Collectively, the number, size, and positional interrelationship of the filtered vents in ONE TRAY® Sealed Sterilization Container creates a unique flow pattern that insures the expeditious dispersal of the sterilizing media throughout the sealed container. In addition, the sloped floor addresses the issue of retained moisture. See Table 1 below for a breakdown of the vent to volume ratios of the various container configurations.

FIGURE 1

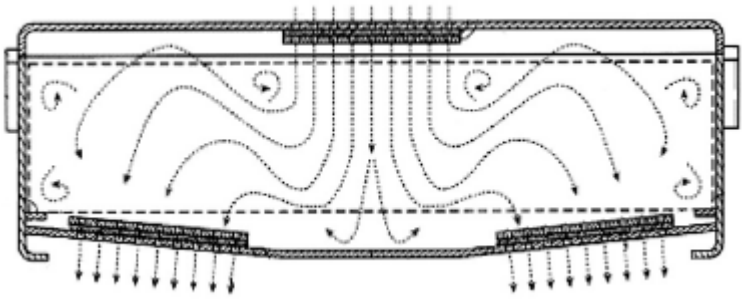


TABLE 1

Model	Vent to Volume Ratio
M2104DT	25.3
M2106DT	38.6
M2108DT	51.8
M2404DT	29.0
M2406DT	44.1
M2408DT	59.3

Microbial Barrier Properties of the Filter

The ONE TRAY® Sealed Sterilization Container utilizes a proprietary set of three SMS filters. These filters act not only as particulate barriers, but also as fluid barriers. The design of the filters ensure proper alignment and use.

5. INDICATIONS FOR USE

The ONE TRAY® Container is a reusable rigid sterilization container intended to be used to enclose reusable medical devices that are to be steam sterilized by a healthcare provider. It is intended to allow sterilization of the enclosed devices and maintenance of sterility of the enclosed devices during storage, transport and until used. This container is compatible for use in the following sterilization modalities in the configuration listed below:

- Prevac Steam
- 270°F, 4 min exposure
- 15-minute dry time

ONE TRAY® is validated to process a twenty five pound (25 lb) gross weight load (single container plus contents). This includes sterilization of lumens (Stainless Steel and Titanium) 1 mm in diameter or larger with lengths of up to 500 mm.

DO NOT STACK ONE TRAY® CONTAINERS DURING STERILIZATION

Examples of validated materials that can be processed within the ONE TRAY®- *Metals:* Stainless Steel, Titanium, Aluminum, *Thermoplastics*: PEEK, Polypropylene, Radel, *Thermosetting Polymers:* Silicone, Phenolic

The ONE TRAY® sealed sterilization container consists of a line of rigid reusable containers listed in the table below. Healthcare Facilities should follow steam sterilization cycle and storage guidelines as stated in AAMI ST79, Comprehensive guide to steam sterilization and sterility assurance in health care facilities.

Model	Model Description
M2104DT	(L) 20.142" x (H) 4.573" x (W) 11.616"
M2106DT	(L) 20.142" x (H) 6.573" x (W) 11.616"
M2108DT	(L) 20.142" x (H) 8.573" x (W) 11.616"
M2404DT	(L) 23.142" x (H) 4.573"x(W)11.616"
M2406DT	(L) 23.142" x (H) 6.573"x(W)11.616"
M2408DT	(L) 23.142" x (H) 8.573" x (W) 11.616"

Sterilization Parameters

Sterilization Parameters for the ONE TRAY® Reusable Sterilization Container			
Sterilization Method	**Cycle Parameters**	**Total System**	**Containers, Accessories & Validated Contents**
Dynamic Air Removal (Pre-Vacuum) Steam	Exposure Temperature: 270°F (132°C) Exposure Time: minimum 4 minutes Dry Time Cycle: 15 minutes Stacking Not Permitted	<25 lbs.	ONE TRAY® Sterilization Container System ONE TRAY® Processing Kit Devices: conjoined and mated surfaces, cannulated, implants and trays/cassettes. Intrinsically Stable Materials: metals, thermoplastics and thermosetting polymers with constant use temperatures above 132°C.

- Examples of device types:
  - Conjoined or mated surfaces devices include: forceps, clamps, compressors, bending pliers, ratchet/ T handles, and retractors.
  - Cannulated devices include: drill bits/ taps, guides, screwdrivers insertion shafts, and cannulated screws.
  - Implant devices include: solid and cannulated screws, connectors, plates and spacers.

- Examples of intrinsically stable materials:
  Metals- Stainless Steel, Titanium alloys and Aluminum.
  Thermoplastics - PEEK, Polypropylene, Radel.
  Thermosetting polymers- Phenolic and Silicone.

ONE TRAY® Sealed Sterilization Container and Accessory Configurations Supported by Validation Data		
	Modality- Dynamic Air Removal (Pre-Vacuum) Steam	
	Contents / Configuration	**Validation Details**
	Devices:	
	Conjoined/ Mated Surfaces	Yes
	Lumen/ Cannulation: Ø3mm x 400mm	Yes
	Lumen/ Cannulation: Ø1mm x 500mm	Yes
	Trays/ Cassettes	Yes
	Materials: Intrinsically stable- metals, thermoplastics and thermosetting polymers with constant use temperatures above 132°C.	Yes
	Accessories	
	(3) Single Use SMS Filters	Yes
	(1) Class 5 Integrator (510(k) K012195)	Yes
	(2) Tamper Evident Seals with indicator dot (510(k) K890763)	Yes
	(2) Load ID Cards	n/a
	Maximum Total Weight (Container plus Contents)	<25 lbs.
	Stacking	Not permitted

ONE TRAY® Sterilization Container Compatibility, Contents, Accessories and Maximum Allowable Weight				
Container	**Graphic Case Dimensions (L x H x W), in.**	**Contents**	**Required Accessories**	**Max. Weight (loaded)**
ONE TRAY® Model	20.142 x 4.573.x.11.616 (Part # M2104DT)	Intrinsically Stable Materials: metals, thermoplastics and thermosetting polymers with constant use temperatures above 132°C. Devices: conjoined and mated surfaces, cannulated (sizes Ø1mm x 500mm), implants and trays/cassettes.	(1) ONE TRAY® Processing Kit (Part # OTK-210)	25 lbs.
	20.142 x 6.573.x.11.616 (Part # M2106DT)			
	20.142 x 8.573.x.11.616 (Part # M2108DT)			
	23.142 x 4.573.x.11.616 (Part # M2404DT)	Intrinsically Stable Materials: metals, thermoplastics and thermosetting polymers with constant use temperatures above 132°C. Devices: conjoined and mated surfaces, cannulated (sizes Ø1mm x 500mm), implants and trays/cassettes.	(1) ONE TRAY® Processing Kit (Part # OTK-210)	25 lbs.
	23.142 x 6.573.x.11.616 (Part # M2406DT)			
	23.142 x 8.573.x.11.616 (Part # M2408DT)			

6. TECHNOLOGICAL CHARACTERISTICS

Below is a table providing a comparison of the technological characteristics between the subject, predicate and reference devices.

Characteristic	**Subject Device- ONE TRAY® Product Code: KCT**	**Predicate Device- Aesculap Aicon (K214041) Product Code: KCT**	**Reference Device- ONE TRAY® (K052567) Product Code: KCT**	**Discussion**
Intended Use	The ONE TRAY Container is a	The AESCULAP Aicon Container is a	ONE TRAY sealed sterilization	Same

	reusable rigid sterilization container intended to be used to enclose reusable medical devices that are to be steam sterilized by a health care provider. It is intended to allow sterilization of the enclosed devices and maintenance of sterility of the enclosed devices during storage, transport and until used.	reusable rigid sterilization container intended to be used to enclose other medical devices that are to be sterilized by a health care provider. It is intended to allow sterilization of the enclosed medical devices and also maintain sterility of the enclosed device during transport and until used.	containers are intended to be used to hold temperature tolerant medical devices, surgical supplies, single instruments, multiple instruments or an instrument set for immediate use following flash sterilization. This includes sterilization of lumens 3mm in diameter or larger with lengths of up to 400mm.	
Sterilization Modalities	Prevac Steam 270°F 4 min Exposure with 15-minute dry time	Prevac Steam 270°F 4 min Exposure with 20-minute dry time Ethylene Oxide, Steris VPRO and Sterrad.	Prevac Steam 270°F 4 min Exposure with NO dry time required	Similar Subject device does not have additional modalities
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	Same
Filter Type & Material	Single use (Polypropylene	Single use (Polypropylene)	Single use (Polypropylene	Same
Container Design	Perforated bottom with perforated lid	Solid bottom with enhanced drying system with Perforated Lid	Perforated bottom with perforated lid	Subject device and reference device have perforated bottoms, whereas the predicate has a solid bottom
Dimensions	(LxHxW) 20.142 x	(LxWxH) 23.25 x	(LxWxH) 20.5 x	Similar size

	4.573.x.11.616” 20.142 x 6.573.x.11.616” 20.142 x 8.573.x.11.616” 23.142 x 4.573.x.11.616” 23.142 x 6.573.x.11.616” 23.142 x 8.573.x.11.616”	11.25 x 4.25” 23.25 x 11.25 x 5.5” 23.25 x 11.25 x 6” 23.25 x 11.25 x 8” 23.25 x 11.25 x 10.5” 18.5 x 11.25 x 4.25” 18.5 x 11.25 x 5.5” 18.5 x 11.25 x 6” 18.5 x 11.25 x 8” 11.75 x 11.25 x 4.25 11.75 x 11.25 x 5.5 11.75 x 11.25 x 6 11.75 x 11.25 x 8 11.75 x 11.25 x 10.5 7.5 x 12.5 x 1.875” 7.5 x 12.5 x 2.5” 7.5 x 12.5 x 3.625” 7.5 x 12.5 x 5.125”	11.5 x 3” 20.5 x 11.5 x 5” 23.5 x 11.5 x 3” 23.5 x 11.5 x 5”	ranges
Maintenance of sterility	365 days	365 days	Immediate Use	Same as predicate device

The subject device and predicate device have the same sterilization cycle parameters and have similar size ranges and materials. The subject device and predicate device have the same 365-day event related storage period.

The predicate device has additional modalities that are not included with the subject device and has a slightly different drying time.

The subject device is the identical device as the reference device with the main differences being related to dry time and 365-day event related storage period.

The subject device and predicate have the same
- steam sterilization cycle parameters
- 365-day event related storage period

The subject device and predicate have the similar
- size ranges and materials
- drying times

The differences are determined to be minor and have no impact on safety and effectiveness based on performance testing and compliance to consensus standards.

7. NONCLINICAL TESTS

The following nonclinical test were performed and summarized in the table below:

Test Name	Method and/or Standard	Acceptance Criteria	Results (Pass / Fail)
Sterilization Efficacy	ANSI / AAMI ST77:2013 ANSI/AAMI TIR12:2010 ISO 17665-1 Sterilization of Healthcare Products – Moist Heat Part 1: Requirements for Development, Validation and Routine Control of a Sterilization Process for Medical Devices.	A sterility assurance level 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
Dry Time	ANSI / AAMI ST77:2013 ANSI/AAMI TIR12:2010 ISO 17665-1 Sterilization of Healthcare Products – Moist Heat Part 1: Requirements for Development, Validation and Routine Control of a Sterilization Process for Medical Devices.	The system shall demonstrate an average pre and post sterilization weight difference of less than 0.2% within five 15 minute cycle completion using final validated parameters and be free of visible moisture.	Pass
Microbial Aerosol Challenge	ANSI / AAMI ST77:2013 ANSI/AAMI TIR12:2010	The container load maintains sterility after exposure to a defined amount of aerosol microorganisms. No presence of growth after incubation period.	Pass
Material Compatibility	AAMI ST98:2022 ANSI/AAMI TIR12:2020	No impact to functionality at the completion of multiple cleaning and sterilization cycles.	Pass
Cytotoxicity	ISO 10993-5:2009	Demonstrate no significant cytotoxic reaction after	Pass

		exposure to sterilant. Using the ISO Elution Method, the response to the article is not greater than 2 (mild reactivity)	
Sterility Maintenance	AAMI ST98:2022 ANSI/AAMI TIR12:2020	Sterility of container contents is maintained after processing for 365 days under conditions which simulate hospital sterile package handling and storage conditions. Biological indicators must be negative for growth after incubation period.	Pass

The subject device was subjected to testing and validations including:

- Shelf Life Study: 365 Day Event Related Shelf Life Study
- Microbial Aerosol Challenge following Pre-Vacuum Steam Sterilization
- Biocompatibility (Cytotoxicity)
- Mechanical Cleaning Validation – Total Organic Carbon (TOC) Analysis
- Mechanical Cleaning Validation – Protein Analysis
- Sterilization Efficacy Study – Half Cycle
- Thermal Profile

The following guidance documents were utilized for the preparation of this submission and decision making regarding testing:

- FDA Guidance- Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling
- AAMI ST77 (FDA recognized consensus standard)

8. CONCLUSION

The conclusions drawn from the nonclinical tests demonstrate that the subject device in 510(k) submission K250029, ONE TRAY® Sealed Sterilization Container, is as safe, as effective, and performs as well as or better than the identified legally marketed predicate device cleared in K214041.