DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

February 10, 2017

Case Medical, Inc.
Tania Lupu
QA-QC Director
19 Empire Blvd.
South Hackensack, New Jersey 07606

Re: K161415
Trade/Device Name: SteriTite® Container System & MediTray Products
Regulation Number: 21 CFR 880.6850
Regulation Name: Sterilization wrap
Regulatory Class: Class II
Product Code: FRG
Dated: January 11, 2017
Received: January 12, 2017

Dear Tania Lupu:

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 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 the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely,

Michael J. Ryan -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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

# Indications for Use

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

510(k) Number *(if known)*
K161415

Device Name

SteriTite® container System & MediTray products

Indications for Use *(Describe)*

The SteriTite® container system with MediTray products is a reusable sterilization container system used to enclose other medical devices, which are to be sterilized, transported and stored by a health care provider. The container consists of a solid or perforated base and perforated lid with filter retention plates, and disposable polypropylene filters. The Case Medical's SteriTite® container system and MediTray products are compatible with the $TSO_3$ Inc.'s STERIZONE® VP4 Cycle 1 sterilization system for blades, lumened devices and flexible endoscopes.

**Table 1. Validated lumen sizes for SteriTite® Container in STERIZONE® VP4 Sterilization.**

| Sterilizer | Cycle | Rigid lumens ≥0.7 mm diameter ≤500 mm length | Flexible lumens ≥1.0 mm diameter ≤850 mm length | Surfaces |
|---|---|---|---|---|
| STERIZONE® VP4 | Cycle 1 | Yes | Yes | Yes |

The SteriTite® Container validated loads of Table 2 are intended to reflect the STERIZONE® VP4 sterilizer cleared under K153689.

**Table 2. Description of SteriTite® Container validated loads**

| Representative of STERIZONE® VP4 Validation Load # (K153689) | **SteriTite® Container Load Description** | **Load weight[1]** [1]Excluding the 25 lb loading rack |
|---|---|---|
| 3 | Validation Load # 1 consisted of flexible endoscopes accommodating three inoculated single channel flexible endoscopes, one per solid bottom container with basket, three containers per load. Flexible endoscopes had an internal channel diameters of 1 mm and lengths of 850 mm. | 12.03 lb / container, 36.1 lb in total |
| 4 | Validation Load # 2 consisted of rigid or semi-rigid channeled devices (12), load accommodating three double channel semi-rigid endoscopes (ureteroscope – 0.7 mm × 500 mm and 1.1 mm × 500 mm) and one length of medical grade stainless steel tubing, placed in three solid bottom containers. Length of tubing: Internal channel diameters of 1.0 mm and lengths of 500 mm. | 11.3 lb / container, 34 lb in total |
| 6 | Validation Load # 3 consisted of three inoculated general medical instruments placed in one solid bottom endo-size (narrow) container including a basket and 3.5 lbs of non-inoculated general medical instruments, representing the following geometries: Distal end (swivel parts), Hinge with screw and Cannulas. | One container of 9.2 lb |

| Representative of STERIZONE® VP4 Validation Load # (K153689) | SteriTite® Container Load Description | Load weight[1]<br><br>[1]Excluding the 25 lb loading rack |
|---|---|---|
| 7a | Validation Load # 7 consisted of three inoculated general medical instruments representing the following geometries: Box-lock hinge, Pivot hinge and Luer-lock. The instruments were placed in three perforated bottom containers including a basket and non-inoculated stainless steel medical devices for a total weight of 20 lb per container. | 20 lb / container, 60 lb in total |
| 7b | Validation load # 4 consisted of five inoculated general medical instruments representing the following geometries: Pivot hinge, Cannula, Locking bridge mechanism, Distal end (cup) and Luer-lock. Instruments were placed in one solid bottom container including three stacked baskets. This container was large enough to include stacked baskets and medical devices to reach a maximum weight of 25 pounds (including container, baskets and inoculated devices). | One container of 25 lb |
| 7c | Validation load # 5 consisted of four inoculated general medical instruments representing the following geometries: Pivot mechanism, Gliding mechanism, Distal end, Proximal lens, Eyepieces (surface) and Luer-lock. Instruments were placed in one solid bottom container including an organization device tray system (four trays system) and two insert boxes.<br>At least one inoculated medical device was added per level of the container. | One container of 20 lb |
| 7d | Validation load # 6 consisted of four inoculated general medical instruments representing the following geometries: Pivot hinge and Luer lock. The instruments represented maximum instrument weight in one perforated bottom container including four stacked baskets. | One container of 25 lb |

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.**

This section applies only to requirements of the Paperwork Reduction Act of 1995.

***DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.***

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
*PRAStaff@fda.hhs.gov*

*"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."*

# 510(K) Summary
# K161415

**SteriTite® container System with MediTray Products forTSO$_3$ Inc.'s STERIZONE® VP4 Sterilizer (Cycle 1)**

**Date Prepared:** 02/10/2017

**Company Name:** Case Medical, Inc; 19 Empire Blvd; South Hackensack, NJ 07606

**Contact:** Tania Lupu, Phone: 201-313-1999 ext.229, Fax: 201-373-9090
Email: tlupu@casemed.com

**Trade Name:** *SteriTite® container System &MediTray* Products

**Common Name:** Sterilization container with disposable filter.

**Regulation number:** 21 CFR 880.6850

**Classification name:** Sterilization Wrap

**Class of Device:** Class II device

**Product Code:** FRG

**Review Panel:** General Hospital

**Establishment Registration Number:** 2248608

**5.1 Substantial Equivalence:**

Case Medical's SteriTite® container system with MediTray Products for TSO$_3$STERIZONE®VP4 Sterilizer (Cycle 1)is substantially equivalent to the SteriTite® container system, previously cleared for:

- Amsco V-PRO hydrogen peroxide sterilizer - 510(k) K090068& K112904
- STERRAD hydrogen peroxide gas plasma sterilizers - 510(k) K991023, K030853, K080558 and K110682
- TSO3 Ozone 125L sterilizers - 510(k) K080558

**5.2 Description of the Device:**

The SteriTite® container system consists of a family of rigid reusable containers and inserts that provide an effective reusable sterilization packaging system for operating room instruments. The *SteriTite*® container for use in STERIZONE® VP4(Cycle 1) is available with solid and perforated base. The container is made out of anodized aluminum with passivated stainless steel hardware and silicone gaskets. Each filter retention plate with gaskets and off set vent pattern secures a disposable filter for bacterial barrier filtration. Filter retention plates and lids and base are interchangeable for universal design. A recessed gasket contributes to a knife edge fit between lid and base. Various instrument trays as well as

stacked baskets and inserts including insert boxes, brackets, posts, partitions and racks provide instrument protection and secure devices for sterilization within the container.

**5.3 Indications for Use:**

The SteriTite® container system with MediTray products is a reusable sterilization container system used to enclose other medical devices, which are to be sterilized, transported and stored by a health care provider. The container consists of a solid or perforated base and perforated lid with filter retention plates, and disposable polypropylene filters. The Case Medical's SteriTite® container system and MediTray products are compatible with the $TSO_3$ Inc.'s STERIZONE® VP4 Cycle 1 sterilization system for blades, lumened devices and flexible endoscopes.

**Table 1. Validated lumen sizes for SteriTite® Container in STERIZONE® VP4 Sterilization.**

| Sterilizer | Cycle | Rigid lumens<br>≥ 0.7 mm diameter<br>≤ 500 mm length | Flexible lumens<br>≥ 1.0 mm diameter<br>≤ 850 mm length | Surfaces |
|---|---|---|---|---|
| STERIZONE® VP4 | Cycle 1 | Yes | Yes | Yes |

The SteriTite® Container validated loads of Table 2 are intended to reflect the STERIZONE® VP4 sterilizer cleared under K153689.

**Table 2. Description of SteriTite® Container validated loads**

| Representative of STERIZONE® VP4 Validation Load #<br><br>(K153689) | **SteriTite® Container Load Description** | **Load weight**[1]<br><br>[1]Excluding the 25 lb loading rack |
|---|---|---|
| 3 | Validation Load # 1 consisted of flexible endoscopes accommodating three inoculated single channel flexible endoscopes, one per solid bottom container with basket, three containers per load. Flexible endoscopes had an internal channel diameters of 1 mm and lengths of 850 mm. | 12.03 lb / container, 36.1 lb in total |
| 4 | Validation Load # 2 consisted of rigid or semi-rigid channeled devices (12), load accommodating three double channel semi-rigid endoscopes (ureteroscope – 0.7 mm × 500 mm and 1.1 mm × 500 mm) and one length of medical grade stainless steel tubing, placed in three solid bottom containers. Length of tubing: Internal channel diameters of 1.0 mm and lengths of 500 mm. | 11.3 lb / container, 34 lb in total |

| | | |
|---|---|---|
| 6 | Validation Load # 3 consisted of three inoculated general medical instruments placed in one solid bottom endo-size (narrow) container including a basket and 3.5 lbs of non-inoculated general medical instruments, representing the following geometries: Distal end (swivel parts), Hinge with screw and Cannulas. | One container of 9.2 lb |

| Representative of STERIZONE® VP4 Validation Load #<br><br>(K153689) | **SteriTite® Container Load Description** | **Load weight**[1]<br><br>[1]Excluding the 25 lb loading rack |
|---|---|---|
| 7a | Validation Load # 7 consisted of three inoculated general medical instruments representing the following geometries: Box-lock hinge, Pivot hinge and Luer-lock. The instruments were placed in three perforated bottom containers including a basket and non-inoculated stainless steel medical devices for a total weight of 20 lb per container. | 20 lb / container, 60 lb in total |
| 7b | Validation load # 4 consisted of five inoculated general medical instruments representing the following geometries: Pivot hinge, Cannula, Locking bridge mechanism, Distal end (cup) and Luer-lock. Instruments were placed in one solid bottom container including three stacked baskets. This container was large enough to include stacked baskets and medical devices to reach a maximum weight of 25 pounds (including container, baskets and inoculated devices). | One container of 25 lb |
| 7c | Validation load # 5 consisted of four inoculated general medical instruments representing the following geometries: Pivot mechanism, Gliding mechanism, Distal end, Proximal lens, Eyepieces (surface) and Luer-lock. Instruments were placed in one solid bottom container including an organization device tray system (four trays system) and two insert boxes.<br>At least one inoculated medical device was added per level of the container. | One container of 20 lb |
| 7d | Validation load # 6 consisted of four inoculated general medical instruments representing the following geometries: Pivot hinge and Luer lock. The instruments represented maximum instrument weight in one perforated bottom container including four stacked baskets. | One container of 25 lb |

**5.4 Description and Recommended Loads:**

The SteriTite® container has been validated with stainless steel and porous lumens, inoculated product, insert boxes, multilevel tray systems, instrument baskets (stacked and single level) with various inserts including brackets, posts and partitions. The container may be used for sterilization of medical devices including full instrument sets and mixed loads.

**Table 2: Recommended Load for SteriTite® Containers with STERIZONE VP4Sterilization**:

| Part Number | Description | Total weight load (lbs) including the sealed container |
|---|---|---|
| SC02M | Mini Size 2”H – Solid Bottom | 6 |
| SC02MG | Mini Size 2”H – Perforated Bottom | 6 |
| SC03M | Mini Size 3”H – Solid Bottom | 8 |
| SC03MG | Mini Size 3”H – Perforated Bottom | 8 |
| SC04M | Mini Size 4”H – Solid Bottom | 8 |
| SC04MG | Mini Size 4”H – Perforated Bottom | 8 |
| SC02N | ¾ Mini Size 2”H – Solid Bottom | 8 |
| SC02NG | ¾ Mini Size 2”H – Perforated Bottom | 8 |
| SC03N | ¾ Mini Size 3”H – Solid Bottom | 10 |
| SC03NG | ¾ Mini Size 3”H – Perforated Bottom | 10 |
| SC04H | ½ Size 4”H – Solid Bottom | 12 |
| SC04HG | ½ Size 4”H – Perforated Bottom | 12 |
| SC05H | Half Size 5”H – Solid Bottom | 12 |
| SC05HG | Half Size 5”H – Perforated Bottom | 12 |
| **Part Number** | **Description** | **Total weight load (lbs) including the sealed container** |
| SC06H | ½ Size 6”H – Solid Bottom | 14 |
| SC06HG | ½ Size 6”H – Perforated Bottom | 14 |
| SC08H | ½ Size 8”H – Solid Bottom | 16 |
| SC08HG | ½ Size 8”H – Perforated Bottom | 16 |
| SC04Q | ¾ Size 4”H – Solid Bottom | 18 |
| SC04QG | ¾ Size 4”H – Perforated Bottom | 18 |
| SC05Q | ¾ Size 5”H – Solid Bottom | 22 |
| SC05QG | ¾ Size 5”H – Perforated Bottom | 22 |
| SC06Q | ¾ Size 6”H – Solid Bottom | 22 |
| SC06QG | ¾ Size 6”H – Perforated Bottom | 22 |
| SC08Q | ¾ Size 8”H – Solid Bottom | 25 |
| SC08QG | ¾ Size 8”H – Perforated Bottom | 25 |
| SC04F | Full Size 4”H – Solid Bottom | 25 |
| SC04FG | Full Size 4”H – Perforated Bottom | 25 |
| SC05F | Full Size 5”H – Solid Bottom | 25 |
| SC05FG | Full Size 5”H – Perforated Bottom | 25 |
| SC06F | Full Size 6”H – Solid Bottom | 25 |
| SC06FG | Full Size 6”H – Perforated Bottom | 25 |
| SC08F | Full Size 8”H – Solid Bottom | 25 |
| SC08FG | Full Size 8”H – Perforated Bottom | 25 |
| SC04L | Long Size 4"H – Solid Bottom | 30 |
| SC04LG | Long Size 4"H – Perforated Bottom | 30 |
| SC06L | Long Size 6"H – Solid Bottom | 30 |

| | | |
|---|---|---|
| SC06LG | Long Size 6"H – Perforated Bottom | 30 |
| SC08L | Long Size 8"H – Solid Bottom | 30 |
| SC08LG | Long Size 8"H – Perforated Bottom | 30 |

**Note:** SteriTite containers for STERIZONE® VP4 Sterilization System are offered in both solid and perforated bottom units. SteriTite containers must be used with single-use non-woven polypropylene disposable filters.

**Table 3. MediTray Products Compatibility Table**

| **MEDITRAY PRODUCT** | **STERIZONE® VP4 Cycle 1 Compatibility** |
|---|---|
| Baskets | Yes |
| Trays | Yes |
| Insert Boxes | Yes |
| Metal Brackets | Yes |
| Metal Partitions | Yes |
| Posts | Yes |
| Silicone Brackets | Yes |
| Racks | Yes |
| Stringers | Yes |

**Table 4. SteriTite® Accessories Compatibility**

| **SteriTite® Accessories** | **STERIZONE® VP4 Compatibility** |
|---|---|
| SCF02 Round filter | Yes |
| SCFM02 Rectangular filter | Yes |
| SCS01W Tamper Evident Seals | Yes |
| SCLH2O23 Load Card Large | Yes |
| SCLH2O24 Load Card Small | Yes |

**5.5 Technological Characteristics (compared to the predicate(s)):**

The SteriTite® container system for STERIZONE® VP4 in Cycle1 is the same SteriTite® container previously cleared for steam, STERRAD 100, 100S, 200, NX, 100NX(Standard and Flex cycles), EtO, Ozone and Hydrogen Peroxide (Amsco V-PRO1) as well as Amsco V-PRO 1Plus and V-PRO Max sterilization. Case Medical's SteriTite® container and MediTray products are compatible with STERIZONE® VP4 in Cycle 1. All containers are same sizes, have gasketed lids with latching mechanism and offer tamper evident features and external indicator as predicate devices. The SteriTite® sealed container in this submission is the same container previously cleared.

**Table of Substantial Equivalence:**

| SteriTite Sealed Container for: | STERIZONE® VP4 Sterilizer | TSO3 125L | AMSCO V-Pro | STERRAD |
|---|---|---|---|---|
| **INDICATIONS FOR USE:** | | | | |
| Intended to enclose medical devices | YES | YES | YES | YES |
| Intended for holding instruments to be sterilized, transported and stored | YES | YES | YES | YES |
| Intended to be reused | YES | YES | YES | YES |
| **DESIGN:** | | | | |
| Rectangular metal container consisting of lid and base | YES | YES | YES | YES |
| Incorporates a filter system to permit entry of sterilant agent and prevent microbial migration during storage | YES | YES | YES | YES |
| Gasketed seal and retention plate | YES | YES | YES | YES |
| Latching mechanism to secure lid and base | YES | YES | YES | YES |
| Tamper evident seal | YES | YES | YES | YES |
| **MATERIALS:** | | | | |
| Container | Anodized Aluminu Stainless Steel, silicone | Anodized Aluminum, Stainless Stee silicone | Anodized Aluminum Stainless Ste silicone | Anodized Aluminum, Stainless Ste silicone |
| Polypropylene Filter | YES | YES | YES | YES |
| **PERFORMANCE STANDARDS/SPECIFICATIONS:** | | | | |
| AAMI ST77 standard testing requirements | YES | YES | YES | YES |
| Permits transfer of contaminated materials | YES | YES | YES | YES |
| **SteriTite Sealed Container for:** | **STERIZONE® VP4 Sterilizer** | **TSO3 125L** | **AMSCO V-Pro** | **STERRAD** |

| | | | | |
|---|---|---|---|---|
| Removable filter | YES | YES | YES | YES |
| Labeling | YES | YES | YES | YES |
| Decontamination | YES | YES | YES | YES |
| Inspection Instructions | YES | YES | YES | YES |
| Sterility maintenance discussed in labeling | YES | YES | YES | YES |
| User responsibilities listed in labeling | YES | YES | YES | YES |
| Routine inspection in labeling | YES | YES | YES | YES |
| **VALIDATION:** | | | | |
| Testing performed using half cycle condition | YES | YES | YES | YES |
| Load | STU load | STU load | STU load | STU load |
| Microbial Barrier | YES | YES | YES | YES |
| **TEST ORGANISM:** | | | | |
| Geobacillusstearothermophilus | YES | YES | YES | YES |
| Inoculated spore carriers with 1 x $10^6$ G. Stearothermophilus | YES | YES | YES | YES |
| Inoculated blades | YES | YES | YES | YES |
| Inoculated lumens | YES | YES | YES | YES |
| Occlusion / matted surfaces | YES | YES | YES | YES |

**5.6 <u>Performance Data</u>:**

All required testing per "Draft Guidance for the Preparation of Premarket Notifications 510(k)'s" was completed. These included:

- "Stacking Capability and Strength Tests" Testing performed demonstrated that containers can be stacked during storage and transport.
- "Lethality Studies" The efficacy studies were performed to determine the sterility effectiveness of the STERIZONE® VP4 sterilizer Cycle1 for surface sterilization, flexible surgical endoscopes single channel with internal channel lumen, single/multi channel rigid endoscopes, as well as non lumened medical devices within the SteriTite® containers with polypropylene disposable filters. Microbial challenges were placed in the most difficult-to-

sterilize areas between mated surfaces, within insert boxes, and between instruments held within silicone brackets and under occlusion. Container configurations and loads representing the worst-case challenge were selected.
Results: All results were negative. Data obtained from representative samples of the *SteriTite*® perforated and solid base container line support SAL of $10^{-6}$ claims.

- "Biocompatibility Study" Irritation testing was conducted for the polypropylene filter material as well as for the silicone brackets material (which is in contact with patient-contacted devices). All results were negative. In addition, levels of residual H2O2 on SteriTite components after processing in STERIZONE VP4 did not exceed the breathing zone.
- "Sterility Maintenance Study" The SteriTite containers sterilized in STERIZONE® VP4 sterilization (Cycle 1) maintained sterility after a six month (180 days) real time with handling events. No growth was observed for the material used to absorb microorganisms of all the containers tested after 31 days and 6 months of shelf life. All the STERIZONE® BI+ Biological indicators placed in the containers were tested and were negative. All chemical indicators (CI+) were lighter than the reference color proving the sterilant penetrated the containers.
- "Microbial Challenge Test" Testing was performed using worst case scenario sample containers. Following the exposure to 100 STERIZONE VP4 sterilization cycles for the highest exposure to sterilant, worst case scenario for material compatibility, the samples containing biological and chemical indicators were processed in a STERIZONE VP4 sterilization cycle. Samples were than subjected to an aerosol challenge ($10^7$ Bacillus Atrophaeus CFU/ml). Each sample met the sterility maintenance requirement as there was no growth at the end of the incubation period.
- "Free Fall Impact Test" Testing performed demonstrated that container can withstand accidental dropping.
- "Handle Stress Test" Testing performed demonstrated that container handles (by design and their means of attachment to the container) are sufficiently robust to support the weight of the container with load (56lbs.) without deformation.
- Internal Stacking**:** In STERIZONE® VP4 Cycle 1 up to four (4) instrument baskets or trays may be stacked within the SteriTite® container system.
- Reuse testing: Validation of material compatibility and functionality was successfully performed after completion of 100 consecutive cleaning and sterilization cycles in STERIZONE® VP4 (Cycle 1)

The SteriTite® container system with MediTray products were fully validated for STERIZONE® VP4 Cycle 1. The validation testing was conducted at qualified independent laboratories in accordance with FDA guidance and available AAMI standards.

### 5.7 Conclusion:

The performance testing data for the subject devices SteriTite® container System &MediTray Products demonstrates the subject devices are as safe, as effective, and performs as well as the predicate devices.