July 31, 2024

Case Medical
Marcia Frieze
CEO
50 West Street
Bloomfield, New Jersey 07003

Re: K240898/S001
Trade/Device Name: SteriTite rigid reusable sterilization container with MediTray Products
Regulation Number: 21 CFR 880.6850
Regulation Name: Sterilization Wrap
Regulatory Class: Class II
Product Code: KCT
Dated: March 25, 2024
Received: April 1, 2024

Dear Marcia Frieze:

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.

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, MS
Assistant Director
Center for Devices and Radiological Health
OHT4: Office of Surgical and Infection Control Devices
Office of Product Evaluation and Quality

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K240898

Device Name

SteriTite rigid reusable sterilization container with MediTray Products

Indications for Use *(Describe)*

The SteriTite container and MediTray products are a reusable sterilization container system to be used to enclose other medical devices, which are to be sterilized, transported, and stored by a health care provider. It is intended to allow sterilization of the enclosed devices and maintain sterility of the enclosed device until it is used. The solid and perforated bottom container configurations are compatible for use with the following low temperature sterilizers and cycles identified below:
- STERIS V-Pro 60: Flexible and Lumen cycle (Solid and perforated bottom container)
- STERIS V-Pro s2: Flexible and Lumen cycle (Solid and perforated bottom container)
- STERIS V-Pro maX 2: Lumen, Non-Lumen and Flexible cycle (Solid and perforated bottom container)
- STERIS V-Pro maX: Lumen, Non-Lumen and Flexible cycle (Solid and perforated bottom container)

☐ Prescription Use (Part 21 CFR 801 Subpart D) ☒ Over-The-Counter Use (21 CFR 801 Subpart C)

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

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Type of Use *(Select one or both, as applicable)*

CONTINUE ON A SEPARATE PAGE IF NEEDED.

The following tables (1-3) identify the sterilizer maximum load weight recommendations with the SteriTite containers in V-Pro sterilization cycles as well as lumen claims per cycle.

Table 1. SteriTite Container in V-Pro s2 and V-Pro 60 including Weight of Container

Part Number	Total Load Weight in V-Pro s2/60 Non-Lumen Cycle	Total Load Weight in V-Pro s2/60 Flexible Cycle
SC02M	25 lbs/11.3kg	11 lbs/4.9kg
SC03M	25 lbs/11.3kg	11 lbs/4.9kg
SC04M	25 lbs/11.3kg	11 lbs/4.9kg
SC02N	25 lbs/11.3kg	11 lbs/4.9kg
SC03N	25 lbs/11.3kg	11 lbs/4.9kg
SC03NL	25 lbs/11.3kg	11 lbs/4.9kg
SC04NL	25 lbs/11.3kg	11 lbs/4.9kg
SC05NL	25 lbs/11.3kg	11 lbs/4.9kg
SC04H	25 lbs/11.3kg	11 lbs/4.9kg
SC05H	25 lbs/11.3kg	11 lbs/4.9kg
SC04Q	25 lbs/11.3kg	11 lbs/4.9kg
SC05Q	25 lbs/11.3kg	11 lbs/4.9kg
SC04F	25 lbs/11.3kg	11 lbs/4.9kg

Table 2. SteriTite Container Maximum Load Weight in V-Pro maX/maX 2 including Weight of Container

Part Number	Total Load Weight in V-Pro maX/maX 2 Lumen Cycle	Total Load Weight in V-Pro maX/maX 2 Flex Cycle	Total Load Weight in V-Pro maX/maX 2 Non-Lumen Cycle
SC02M	19.65 lbs/ 8.9kg	24 lbs/11kg	50 lbs/22.6kg
SC03M	19.65 lbs/ 8.9kg	24 lbs/11kg	50 lbs/22.6kg
SC04M	19.65 lbs/ 8.9kg	24 lbs/11kg	50 lbs/22.6kg
SC02N	19.65 lbs/ 8.9kg	24 lbs/11kg	50 lbs/22.6kg
SC03N	19.65 lbs/ 8.9kg	24 lbs/11kg	50 lbs/22.6kg
SC03NL	19.65 lbs/ 8.9kg	24 lbs/11kg	50 lbs/22.6kg
SC04NL	19.65 lbs/ 8.9kg	24 lbs/11kg	50 lbs/22.6kg
SC05NL	19.65 lbs/ 8.9kg	24 lbs/11kg	50 lbs/22.6kg
SC04H	19.65 lbs/ 8.9kg	24 lbs/11kg	50 lbs/22.6kg
SC05H	19.65 lbs/ 8.9kg	24 lbs/11kg	50 lbs/22.6kg
SC06H	19.65 lbs/ 8.9kg	24 lbs/11kg	50 lbs/22.6kg
SC08H	19.65 lbs/ 8.9kg	24 lbs/11kg	50 lbs/22.6kg
SC04Q	19.65 lbs/ 8.9kg	24 lbs/11kg	50 lbs/22.6kg
SC05Q	19.65 lbs/ 8.9kg	24 lbs/11kg	50 lbs/22.6kg
SC06Q	19.65 lbs/ 8.9kg	24 lbs/11kg	50 lbs/22.6kg
SC08Q	19.65 lbs/ 8.9kg	24 lbs/11kg	50 lbs/22.6kg
SC04F	19.65 lbs/ 8.9kg	24 lbs/11kg	50 lbs/22.6kg
SC05F	19.65 lbs/ 8.9kg	24 lbs/11kg	50 lbs/22.6kg
SC06F	19.65 lbs/ 8.9kg	24 lbs/11kg	50 lbs/22.6kg
SC08F	19.65 lbs/ 8.9kg	24 lbs/11kg	50 lbs/22.6kg
SC04L	19.65 lbs/ 8.9kg	24 lbs/11kg	50 lbs/22.6kg
SC06L	19.65 lbs/ 8.9kg	24 lbs/11kg	50 lbs/22.6kg
SC08L	19.65 lbs/ 8.9kg	24 lbs/11kg	50 lbs/22.6kg
SC05W	19.65 lbs/ 8.9kg	24 lbs/11kg	50 lbs/22.6kg

Table 3. Sterilant penetration for channel lumens using solid bottom container in STERIS V-Pro sterilization

Sterilizer	Cycle	Lumen Sterilization Claims (I.D. x Length)
STERIS V-Pro 60	Flexible	≥1mm x ≤990mm: Single or Dual Lumen (Solid Bottom)*
STERIS V-Pro 60	Lumen	≥0.77mm x ≤527mm: Dual Channel (Solid Bottom)**
STERIS V-Pro s2	Flexible	≥1mm x ≤990mm: Single or Dual Lumen (Solid Bottom)
STERIS V-Pro s2	Lumen	≥0.77mm x ≤527mm: Dual Channel (Solid Bottom)
STERIS V-Pro maX 2	Flexible	≥1mm x ≤1050mm: Single Lumen (Solid Bottom)
STERIS V-Pro maX 2	Lumen	≥0.77mm x ≤527mm: Dual Channel (Solid Bottom)
STERIS V-Pro maX	Flexible	≥1mm x ≤1050mm: Single Lumen (Solid Bottom)
STERIS V-Pro maX	Lumen	≥0.77mm x ≤527mm: Dual Channel (Solid Bottom)

510K Summary K240898

SteriTite rigid reusable sterilization container with MediTray Products

Date Prepared :	03/25/2024
Company Name :	Case Medical, Inc 50 West Street Bloomfield NJ 07003
Contact:	Marcia Frieze
Email	MFrieze@casemed.com
Office	201-313-1999 x 225
Fax	201-373-9090
Trade Name	SteriTite Container System with MediTray Products
Common Name	SteriTite Universal Container System
Class of Device	Class II
Product Code	KCT
Review Panel	General Hospital
Establishment Registration Number	2248608
Predicate Device	K212711 -SteriTite Rigid Container Sterilization System with and MediTray products
Description of Device	The SteriTite® Universal 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, as previously cleared, is available with solid or perforated base. The container is made of anodized aluminum with passivated stainless-steel hardware and silicone gaskets, disposable single use filter, tamper evident seal, and perforated vents for sterilant penetration and air removal.

10.3 Indications for Use Summary

The SteriTite container and MediTray products are a reusable sterilization container system to be used to enclose other medical devices, which are to be sterilized, transported, and stored by a health care provider. It is intended to allow sterilization of the enclosed devices and maintain sterility of the enclosed device until it is used. The solid and perforated bottom container configurations are compatible for use with the following low temperature sterilizers and cycles identified below:

- STERIS V-Pro 60: Flexible and Lumen cycle (Solid and perforated bottom container)
- STERIS V-Pro s2: Flexible and Lumen cycle (Solid and perforated bottom container)
- STERIS V-Pro maX 2: Lumen, Non-Lumen and Flexible cycle (Solid and perforated bottom container)
- STERIS V-Pro maX: Lumen, Non-Lumen and Flexible cycle (Solid and perforated bottom container)

The following table (Table 1) displays the SteriTite part numbers and the sterilizers they are compatible with:

Table 1. SteriTite Solid Bottom Container Compatibility with Low Temperature and Pre vacuum Steam Sterilizers.

Part Number	Description	V-Pro maX/maX 2	V-Pro s2/60
SC02M	2" High Mini-Size Solid Base	Yes	Yes
SCO3M	3" High Mini-Size Solid Base	Yes	Yes
SCO4M	4" High Mini-Size Solid Base	Yes	Yes
SC02N	2" High Narrow-Size Solid Base	Yes	Yes
SC03N	3" High Narrow-Size Solid Base	Yes	Yes
SC03NL	3" High Narrow Long-Size Solid Base	Yes	Yes
SC04NL	4" High Narrow Long-Size Solid Base	Yes	Yes
SC05NL	5" High Narrow Long -Size Solid Base	Yes	Yes
SC04H	4" High Half-Size w/ Solid Base	Yes	Yes
SC05H	5" High Half-size w/ Solid Base	Yes	Yes
SC06H	6" High Half-Size w/ Solid Base	Yes	N/A
SC08H	8" High Half-Size w/ Solid Base	Yes	N/A
SC04Q	4" High 3/4 Size w/ Solid Base	Yes	Yes
SC05Q	5" High 3/4 Size w/ Solid Base	Yes	Yes
SC06Q	6" High 3/4 Size w/ Solid Base	Yes	N/A
SC08Q	8" High 3/4 Size w/ Solid Base	Yes	N/A
SC04F	4" High Full-size w/ Solid Base	Yes	Yes
SC05F	5" High Full-size w/ Solid Base	Yes	N/A
SC06F	6" High Full-size w/ Solid Base	Yes	N/A
SC08F	8" High Full-size w/ Solid Base	Yes	N/A
SC04L	4" High Long-size w/ Solid Base	Yes	N/A
SC06L	6" High Long-size w/ Solid Base	Yes	N/A
SC08L	8" High Long-size w/ Solid Base	Yes	N/A
SC05W	5" High Long Size w/ Solid Base	Yes	N/A

The following table (Table 2) identifies which MediTray products are compatible with low temperature sterilizers and steam sterilization:

Table 2. MediTray Compatibility with Low Temp. Sterilizers & Steam Containerized and Wrapped

MediTray Product	V-Pro maX/2	V-Pro s2/60	STERIZONE VP4	STERRAD NX/ 100 NX	Steam
Baskets	Yes	Yes	Yes	Yes	Yes
Trays	Yes	Yes	Yes	Yes	Yes
Insert Boxes	Yes	Yes	Yes	Yes	Yes
Metal Brackets	Yes	Yes	Yes	Yes	Yes
Metal Partitions	Yes	Yes	Yes	Yes	Yes
Posts	Yes	Yes	Yes	Yes	Yes
Silicone Brackets	Yes	Yes	Yes	Yes	Yes
Racks	Yes	Yes	Yes	Yes	Yes
Stringers	Yes	Yes	Yes	Yes	Yes

The following table (Table 3) identifies which SteriTite accessories are compatible with low temperature sterilization:

Table 3. SteriTite Consumables for Low Temperature

SteriTite Disposables	Steris V-Pro maX/maX2	V-Pro s2/60
SCF02 Round Polypro* filter	Yes	Yes
SCFM02 Rectangular Polypro* filter	Yes	Yes
SCS01W Tamper Evident Seal White	Yes	Yes
SCLH2O23 Load Card Large	Yes	Yes
SCLH2O24 Load Card Small	Yes	Yes

**PolyPro is a non-woven polypropylene filter material that must be used for vaporized hydrogen peroxide and gas plasma. It may be used for steam sterilization. Use round filters for standard container sizes, rectangular filters for mini, narrow, and narrow long containers.*

The following tables (4-5) identify the sterilizer maximum load weight recommendations with the SteriTite containers in Low temperature sterilization:

Table 4. SteriTite Container in V-Pro s2 and V-Pro 60 including Weight of Container

Part Number	Total Load Weight in V-Pro s2/60 Non-Lumen Cycle	Total Load Weight in V-Pro s2/60 Flexible Cycle
SC02M	25 lbs/11.3kg	11 lbs/4.9kg
SC03M	25 lbs/11.3kg	11 lbs/4.9kg
SC04M	25 lbs/11.3kg	11 lbs/4.9kg
SC02N	25 lbs/11.3kg	11 lbs/4.9kg
SC03N	25 lbs/11.3kg	11 lbs/4.9kg
SC03NL	25 lbs/11.3kg	11 lbs/4.9kg
SC04NL	25 lbs/11.3kg	11 lbs/4.9kg
SC05NL	25 lbs/11.3kg	11 lbs/4.9kg
SC04H	25 lbs/11.3kg	11 lbs/4.9kg
SC05H	25 lbs/11.3kg	11 lbs/4.9kg
SC04Q	25 lbs/11.3kg	11 lbs/4.9kg
SC05Q	25 lbs/11.3kg	11 lbs/4.9kg
SC04F	25 lbs/11.3kg	11 lbs/4.9kg

Table 5. SteriTite Container Maximum Load Weight in V-Pro maX/maX 2 including Weight of Container

Part Number	Total Load Weight in V-Pro maX/maX 2 Lumen Cycle	Total Load Weight in V-Pro maX/maX 2 Flex Cycle	Total Load Weight in V-Pro maX/maX 2 Non-Lumen Cycle
SC02M	19.65 lbs/ 8.9kg	24 lbs/11kg	50 lbs/22.6kg
SC03M	19.65 lbs/ 8.9kg	24 lbs/11kg	50 lbs/22.6kg
SC04M	19.65 lbs/ 8.9kg	24 lbs/11kg	50 lbs/22.6kg
SC02N	19.65 lbs/ 8.9kg	24 lbs/11kg	50 lbs/22.6kg
SC03N	19.65 lbs/ 8.9kg	24 lbs/11kg	50 lbs/22.6kg
SC03NL	19.65 lbs/ 8.9kg	24 lbs/11kg	50 lbs/22.6kg
SC04NL	19.65 lbs/ 8.9kg	24 lbs/11kg	50 lbs/22.6kg
SC05NL	19.65 lbs/ 8.9kg	24 lbs/11kg	50 lbs/22.6kg
SC04H	19.65 lbs/ 8.9kg	24 lbs/11kg	50 lbs/22.6kg
SC05H	19.65 lbs/ 8.9kg	24 lbs/11kg	50 lbs/22.6kg
SC06H	19.65 lbs/ 8.9kg	24 lbs/11kg	50 lbs/22.6kg
SC08H	19.65 lbs/ 8.9kg	24 lbs/11kg	50 lbs/22.6kg
SC04Q	19.65 lbs/ 8.9kg	24 lbs/11kg	50 lbs/22.6kg
SC05Q	19.65 lbs/ 8.9kg	24 lbs/11kg	50 lbs/22.6kg
SC06Q	19.65 lbs/ 8.9kg	24 lbs/11kg	50 lbs/22.6kg
SC08Q	19.65 lbs/ 8.9kg	24 lbs/11kg	50 lbs/22.6kg
SC04F	19.65 lbs/ 8.9kg	24 lbs/11kg	50 lbs/22.6kg
SC05F	19.65 lbs/ 8.9kg	24 lbs/11kg	50 lbs/22.6kg
SC06F	19.65 lbs/ 8.9kg	24 lbs/11kg	50 lbs/22.6kg
SC08F	19.65 lbs/ 8.9kg	24 lbs/11kg	50 lbs/22.6kg
SC04L	19.65 lbs/ 8.9kg	24 lbs/11kg	50 lbs/22.6kg
SC06L	19.65 lbs/ 8.9kg	24 lbs/11kg	50 lbs/22.6kg
SC08L	19.65 lbs/ 8.9kg	24 lbs/11kg	50 lbs/22.6kg
SC05W	19.65 lbs/ 8.9kg	24 lbs/11kg	50 lbs/22.6kg

Indications For Use Comparison

The device has no different indication for use than the predicate (K212711). The SteriTite rigid reusable sealed container system with solid base is equivalent to the SteriTite container with perforated base (predicate) previously cleared for compatibility with Steris V-Pro Sterilizers, including Steris V-Pro maX (K112904), V-Pro maX 2, V-Pro s2, V-Pro 60 (K221492, K212711). Case Medical adheres to the overkill principle for sterilization validation testing. As a worst-case scenario, half cycles are utilized, as are end of shelf-life concentrations of hydrogen peroxide for low temperature sterilization validation. The SteriTite container system has also been previously cleared for compatibility with other various low temperature sterilizers as well as steam sterilization. All functional and design characteristics are the same as the predicate previously cleared and show equivalent performance characteristics. The SteriTite container system with MediTray products presented in the current submission shares the same technological characteristics as the previously cleared SteriTite container and MediTray products. This includes anodized lid and base, passivated stainless steel hardware, gasketed seal between lid and base, platinum cured silicone gaskets, perforated vent pattern on the lid, utilizing polypropylene filters (polypropylene filters specified for H2O2 sterilizers), tamper evident latching mechanism, and one year shelf life (365 days) for sterility maintenance

Technological Comparison

Table 6. Technological Characteristics of Predicate and Subject Device

Technological Characteristics	**Predicate**	**Subject Device**
Anodized aluminum lid and base	Same	Same
Passivated stainless steel hardware	Same	Same
Platinum cured silicone gaskets	Same	Same
Perforated vent pattern on lid	Same	Same
Perforated vent pattern on base	Yes	Different
Interchangeable filter retention plate	Same	Same
Polypropylene single use filters	Same	Same
Tamper evident latching mechanism	Same	Same
One year shelf-life sterility maintenance	Same	Same
Pre-Vacuum Steam Sterilization	Same	Same
Low Temperature Sterilization (V-Pro)	Same	Same

The following tables (6a-6d) list the substantial equivalence of the previously cleared perforated bottom SteriTite container with MediTray products (predicate) K212711 and the solid base SteriTite container system and MediTray products (subject device).

Table 6a Indications for Use

INDICATIONS FOR USE:	**Predicate**	**Subject Device**
Intended to enclose medical devices	Same	Same
Intended for holding instruments to be sterilized, transported, and stored	Same	Same
Intended to be reused	Same	Same
Protect instruments from damage	Same	Same
Maintain the sterility of enclosed medical devices	Same	Same
Provide a barrier to microorganisms	Same	Same

Table 6b Device Design

DESIGN:	**Predicate**	**Subject Device**
Rectangular anodized aluminum container consisting of lid and base	Same	Same
Recessed gasket seal between lid and base	Same	Same
Filter system to permit entry of sterilant agent and exit	Same	Same
Off set retention plate	Same	Same
Microbial barrier migration	Same	Same
Interchangeable filter retention plates with gasket	Same	Same
Latching mechanism to secure lid and base	Same	Same
Tamper-proof locking mechanisms	Same	Same
Handles for ease of transport	Same	Same
Passivated stainless-steel hardware	Same	Same
A knife edge fit between lid and base.	Same	Same
Various instrument trays to correspond with container	Same	Same
Organizational inserts	Same	Same
Internal and external stacking	Same	Same
Aseptic presentation of contents	Same	Same

Table 6c Performance Standards/Specifications

PERFORMANCE STANDARDS/ SPECIFICATIONS:	Predicate	Subject Device
Sterile barrier system	Same	Same
Secure transport of sterilized contents to point of use	Same	Same
Shelf life 365 days/ 1year of sterility maintenance	Same	Same
Dry outcome in all methods of sterilizations	Same	Same
Corrosion resistant seal	Same	Same
Inspection Instructions included in labeling	Same	Same
Durable construction for long use life	Same	Same
User responsibilities listed in labeling	Same	Same
Remain sealed until opened	Same	Same
The filter retention plates audibly click to lock into place	Same	Same
Tamper evident seals on latches provide visual evidence of sterility breach	Same	Same
Lid and bottom are made of anodized aluminum making them lightweight	Same	Same

Table 6d Validation

VALIDATION:	Predicate	Subject Device
Half Cycle Test Conditions	Same	Same
Maximum Load Test	Same	Same
Microbial Barrier	Same	Same
Test Organism G. Stearothermophilus	Same	Same
Simulated Use Test	Same	Same
Inoculated blades	Same	Same
Inoculated lumens	Same	Same
Occlusion / matted surfaces	Same	Same
Sterilization of single and dual lumen devices	Same	Same
Testing in lumen, non-lumen, and flexible cycles	Same	Same

Non-Clinical Performance Testing

Case Medical, Inc. follows the "overkill method" of sterility assurance to show an elimination of a biological challenge.All SteriTite containers were tested with inner baskets or trays representative of the MediTray line of products. Testing was designed to simulate worst-case scenarios with half cycles utilized with end of shelf-life concentrations of hydrogen peroxide for low temperature sterilization. The bacterial strain G. stearothermophilus was used in all testing due to its resistance to moist heat and hydrogen peroxide. The validation testing was conducted at qualified independent laboratories in accordance with FDA guidance and available ANSI/AAMI standards such as ANSI/AAMI ST77, AAMI TIR 12 and ANSI/AMMI ST-79. Results are summarized in Table 7 below.

Table 7. Summary of Performance Testing

The solid bottom container is substantially equivalent to the perforated bottom container. However, it has greater performance features for sterility maintenance and for maintaining a microbial barrier as there are no perforations or vents in the bottom of the container.

Performance Testing	Standard	Purpose	Results
Sterility Maintenance	ANSI/AAMI ST77:2013 (R)2018	Demonstrate the integrity of the container to maintain sterility of contents over time and with multiple handling events after sterilization.	Pass
Whole Package Microbial Challenge	ANSI/AAMI ST77:2013 (R)2018	Demonstration of whole package integrity following exposure to aerosolized bacteria spores.	Pass
Biocompatibility	ANSI AAMI ISO10993- 1	Acute systemic toxicity, primary irritation and sensitization of the subject device.	Pass
Material Compatibility / Re- Use Testing	ANSI/AAMI ST77:2013 (R)2018	Demonstration that the subject device materials are compatible with the intended sterilization cycles.	Pass
Simulated Use Testing/Sterilization Efficacy	ANSI AAMI ISO 14937:2009/(R)2013	Demonstrated sterilization efficacy of the subject device for processing medical devices using the identified sterilization processes.	Pass

Table 8. Sterilant penetration

Test Device	Predicate	Subject Device
General instrumentation	Same	Same
Single/double channel flexible endoscopes	Same	Same
Single/double channel rigid endoscopes	Same	Same
Closed-end Cannula	N/A	Pass

Table 9. Sterilant penetration for channel lumens using solid bottom container in low temperature sterilization and steam

Sterilizer	Cycle	Lumen Sterilization Claims (I.D. x Length)
STERIS V-Pro 60	Flexible	≥1mm x ≤990mm: Single or Dual Lumen (Solid Bottom)*
STERIS V-Pro 60	Lumen	≥0.77mm x ≤527mm: Dual Channel (Solid Bottom)**
STERIS V-Pro s2	Flexible	≥1mm x ≤990mm: Single or Dual Lumen (Solid Bottom)
STERIS V-Pro s2	Lumen	≥0.77mm x ≤527mm: Dual Channel (Solid Bottom)
STERIS V-Pro maX 2	Flexible	≥1mm x ≤1050mm: Single Lumen (Solid Bottom)
STERIS V-Pro maX 2	Lumen	≥0.77mm x ≤527mm: Dual Channel (Solid Bottom)
STERIS V-Pro maX	Flexible	≥1mm x ≤1050mm: Single Lumen (Solid Bottom)
STERIS V-Pro maX	Lumen	≥0.77mm x ≤527mm: Dual Channel (Solid Bottom)
Sterizone VP4	Cycle 1	≥1.2mm x ≤1955mm: Flexible Lumens (Solid Bottom)
Sterizone VP4	Cycle 1	≥1.45mm x ≤3500mm: Flexible Lumens (Solid Bottom)
Steam	Pre-Vac	≥2mm x ≤400mm: Stainless Steel Lumen (Solid Bottom) ≥1.2mm x ≤400mm: Flexible Lumen (Solid Bottom)

*****The validation study in the flexible cycle utilized lumens of 0.48 mm I.D x 100 mm L.
Additional lumens in the load were 1.0mm I.D x 1050 mm L. *(Attachment 013- Steris Lab Report 14463393.A)*
****** ≥ 0.8mm ID and ≤ 542 mm in length lumens have been shown to be equivalent to be equivalent for validation testing purposes to the predicate ≥0.77mm ID and ≤527mm in length *(Attachment 011- Steris Lab report 14463391.A).*

Conclusion

The conclusion drawn from the nonclinical performance tests demonstrate that the subject device in this 510(k) submission for the SteriTite Container System and MediTray Products, is as safe, as effective, and performs as well as or better than the legally marketed predicate device cleared under K212711.

The solid bottom container has been previously cleared in pre-vacuum steam, EO, VP4 sterilizer and received FDA 510k clearance. This submission is for compatibility of the SteriTite solid bottom container system in the V-Pro maX , V-Pro maX2, V-Pro s2 and the V-Pro 60 sterilizer. The solid bottom container is substantially equivalent to the perforated bottom container previously cleared. However, it has greater performance features for sterility maintenance and for maintaining a microbial barrier as there are no perforations or vents in the bottom of the container. SteriTite Universal Container System and MediTray Products is as safe, as effective, and performs as well as or better than the legally marketed predicate device cleared under K212711.

All functional and design characteristics are the same as the predicate previously cleared in K212711 and show equivalent performance characteristics. The SteriTite container system with solid base for this submission is the same container system that has been previously cleared for steam and low temperature sterilization with perforated base. The solid base line of SteriTite container systems has only perforations on the lid compared to the predicate which has perforations in lid and base. Therefore, there are fewer inlets for microbial ingression. The solid bottom line of SteriTite container systems demonstrated the same technical and performance characteristics in the V-Pro maX, V-Pro maX 2, V-Pro s2, and V-Pro 60 as the predicate. The functional and design characteristics are the same as the predicate previously cleared and show equivalent performance characteristics.