June 13, 2018

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

Re: K173259
Trade/Device Name: Case Medical SteriTite Reusable Rigid Sterilization Container System with MediTray accessories
Regulation Number: 21 CFR 880.6850
Regulation Name: Sterilization Wrap
Regulatory Class: Class II
Product Code: KCT
Dated: March 26, 2018
Received: March 28, 2018

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.

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,

Elizabeth F. Claverie -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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K173259

Device Name
SteriTite® Container System with MediTray® Products

Indications for Use *(Describe)*
The SteriTite® container system with MediTray® products is a rigid reusable sealed 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 a perforated base, perforated lid with filter retention plates, and disposable filters. Case Medical endorses a dry outcome for sterilization, transport, storage, and subsequent use.

The SteriTite® container has been validated for prevacuum sterilization at 132°C for 4 minutes. with 3 stainless steel (3mm inner diameter × 400mm length) and 3 porous lumens (2mm inner diameter × 400mm length), and representative products of the MediTray line of accessories such as: 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, stacked trays, and mixed loads.

Additionally, the SteriTite® container has been validated for prevacuum sterilization at 134°C for 4 minutes using tabletop autoclaves for metal instrument loads with 5 stainless steel lumen (2mm ID × 250mm length).

The following claims have been validated for this device:

• One (1) Year sterile shelf life/maintenance of sterility claim:
• Reduced Dry Time Claim for Pre-Vacuum Steam Sterilization: SteriTite® containers previously cleared for terminal and IUSS (flash) steam sterilization may be used for storage and transport after steam sterilization with a reduced dry time. Dry loads will be achieved using a minimum of 5 minutes dry time when using perforated bottom units and a minimum of 8 minutes dry time when using solid bottom units.
• Compatibility with Table Top Pre-Vacuum Steam Sterilization: SteriTite® containers previously cleared for steam sterilization may be used in small table top sterilizers with dynamic air removal. Container sizes are limited due to the small chamber of the table top sterilizer.
The SteriTite® container system is recommended to be used for sterilization of medical devices. Please see tables 1 and 2 below for the recommended total weight of SteriTite® containers with contents in steam sterilization:

Table 1: Recommended Load for SteriTite® Containers in Steam Sterilization:

Part Number	Description	Total weight load including container
SC02M	Mini Size 2”H – Solid Bottom	6 lbs. (2.7 kg)
SC02MG	Mini Size 2”H – Perforated Bottom	6 lbs. (2.7 kg)
SC03M	Mini Size 3”H – Solid Bottom	8 lbs. (3.6 kg)
SC03MG	Mini Size 3”H – Perforated Bottom	8 lbs. (3.6 kg)
SC04M	Mini Size 4”H – Solid Bottom	8 lbs. (3.6 kg)
SC04MG	Mini Size 4”H – Perforated Bottom	8 lbs. (3.6 kg)
SC02N	¾ Mini Size 2”H – Solid Bottom	8 lbs. (3.6 kg)
SC02NG	¾ Mini Size 2”H – Perforated Bottom	8 lbs. (3.6 kg)
SC03N	¾ Mini Size 3”H – Solid Bottom	10 lbs. (4.5 kg)
SC03NG	¾ Mini Size 3”H – Perforated Bottom	10 lbs. (4.5 kg)
SC04H	½ Size 4”H – Solid Bottom	12 lbs. (5.4 kg)
SC04HG	½ Size 4”H – Perforated Bottom	12 lbs. (5.4 kg)
SC05H	Half Size 5”H – Solid Bottom	12 lbs. (5.4 kg)

SC05HG	Half Size 5”H – Perforated Bottom	12 lbs. (5.4 kg)
SC06H	½ Size 6”H – Solid Bottom	14 lbs. (6.4 kg)
SC06HG	½ Size 6”H – Perforated Bottom	14 lbs. (6.4 kg)
SC08H	½ Size 8”H – Solid Bottom	16 lbs. (7.3 kg)
SC08HG	½ Size 8”H – Perforated Bottom	16 lbs. (7.3 kg)
SC04Q	¾ Size 4”H – Solid Bottom	18 lbs. (8.2 kg)
SC04QG	¾ Size 4”H – Perforated Bottom	18 lbs. (8.2 kg)
SC05Q	¾ Size 5”H – Solid Bottom	22 lbs. (10.0 kg)
SC05QG	¾ Size 5”H – Perforated Bottom	22 lbs. (10.0 kg)
SC06Q	¾ Size 6”H – Solid Bottom	22 lbs. (10.0 kg)
SC06QG	¾ Size 6”H – Perforated Bottom	22 lbs. (10.0 kg)
SC08Q	¾ Size 8”H – Solid Bottom	25 lbs. (11.3 kg)
SC08QG	¾ Size 8”H – Perforated Bottom	25 lbs. (11.3 kg)
SC04F	Full Size 4”H – Solid Bottom	25 lbs. (11.3 kg)
SC04FG	Full Size 4”H – Perforated Bottom	25 lbs. (11.3 kg)
SC05F	Full Size 5”H – Solid Bottom	25 lbs. (11.3 kg)
SC05FG	Full Size 5”H – Perforated Bottom	25 lbs. (11.3 kg)
SC06F	Full Size 6”H – Solid Bottom	25 lbs. (11.3 kg)
SC06FG	Full Size 6”H – Perforated Bottom	25 lbs. (11.3 kg)
SC08F	Full Size 8”H – Solid Bottom	25 lbs. (11.3 kg)
SC08FG	Full Size 8”H – Perforated Bottom	25 lbs. (11.3 kg)
SC04L	Long Size 4"H – Solid Bottom	30 lbs. (13.6 kg)
SC04LG	Long Size 4"H – Perforated Bottom	30 lbs. (13.6 kg)
SC06L	Long Size 6"H – Solid Bottom	30 lbs. (13.6 kg)
SC06LG	Long Size 6"H – Perforated Bottom	30 lbs. (13.6 kg)
SC08L	Long Size 8"H – Solid Bottom	30 lbs. (13.6 kg)
SC08LG	Long Size 8"H – Perforated Bottom	30 lbs. (13.6 kg)

Table 2. Recommended Load and Sizing for SteriTite® Containers for Table Top Sterilizers

Part Number	Description	Total weight load including container
SC02M	Mini Size 2”H – Solid Bottom	6 lbs. (2.7 kg)
SC02MG	Mini Size 2”H – Perforated Bottom	6 lbs. (2.7 kg)
SC03M	Mini Size 3”H – Solid Bottom	8 lbs. (3.6 kg)
SC03MG	Mini Size 3”H – Perforated Bottom	8 lbs. (3.6 kg)
SC04M	Mini Size 4”H – Solid Bottom	8 lbs. (3.6 kg)
SC04MG	Mini Size 4”H – Perforated Bottom	8 lbs. (3.6 kg)
SC02N	¾ Mini Size 2”H – Solid Bottom	8 lbs. (3.6 kg)
SC02NG	¾ Mini Size 2”H – Perforated Bottom	8 lbs. (3.6 kg)
SC03N	¾ Mini Size 3”H – Solid Bottom	10 lbs. (4.5 kg)
SC03NG	¾ Mini Size 3”H – Perforated Bottom	10 lbs. (4.5 kg)

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

SteriTite® Container System with MediTray Products

Date Prepared: 6/05/2018

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 with MediTray Products

Common Name: Sterilization container with disposable filter

Regulation number: 21 CFR 880.6850

Classification name: Sterilization Wrap Containers, Trays, Cassettes & Other Accessories

Class of Device: Class II

Product Code: KCT

Review Panel: General Hospital

Establishment Registration Number: 2248608

Predicate device: K022978 - SteriTite Rigid sterilization Containerr System with FlashTite valve plate & MediTray Products

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 as previously cleared is available with solid or 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 in lid and base are interchangeable for universal use. 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 rigid reusable sealed 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 a perforated base, perforated lid with filter

retention plates, and disposable filters. Case Medical endorses a dry outcome for sterilization, transport, storage, and subsequent use.

The SteriTite® container has been validated for prevacuum sterilization at 132°C for 4 minutes. with 3 stainless steel (3mm inner diameter × 400mm length) and 3 porous lumens (2mm inner diameter × 400mm length), and representative products of the MediTray line of accessories such as: 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, stacked trays, and mixed loads.

Additionally, the SteriTite® container has been validated for prevacuum sterilization at 134°C for 4 minutes using tabletop autoclaves for metal instrument loads with 5 stainless steel lumen (2mm ID × 250mm length).

The following claims have been validated for this device:

• One (1) Year sterile shelf life/maintenance of sterility claim:
• Reduced Dry Time Claim for Pre-Vacuum Steam Sterilization: SteriTite® containers previously cleared for terminal and IUSS (flash) steam sterilization may be used for storage and transport after steam sterilization with a reduced dry time. Dry loads will be achieved using a minimum of 5 minutes dry time when using perforated bottom units and a minimum of 8 minutes dry time when using solid bottom units.
• Compatibility with Table Top Pre-Vacuum Steam Sterilization: SteriTite® containers previously cleared for steam sterilization may be used in small table top sterilizers with dynamic air removal. Container sizes are limited due to the small chamber of the table top sterilizer.
The SteriTite® container system is recommended to be used for sterilization of medical devices. Please see tables 1 and 2 below for the recommended total weight of SteriTite® containers with contents in steam sterilization:

Table 1: Recommended Load for SteriTite® Containers in Low Temperature and Steam Sterilization:

Part Number	Description	Total weight load including container
SC02M	Mini Size 2”H – Solid Bottom	6 lbs. (2.7 kg)
SC02MG	Mini Size 2”H – Perforated Bottom	6 lbs. (2.7 kg)
SC03M	Mini Size 3”H – Solid Bottom	8 lbs. (3.6 kg)
SC03MG	Mini Size 3”H – Perforated Bottom	8 lbs. (3.6 kg)
SC04M	Mini Size 4”H – Solid Bottom	8 lbs. (3.6 kg)
SC04MG	Mini Size 4”H – Perforated Bottom	8 lbs. (3.6 kg)
SC02N	¾ Mini Size 2”H – Solid Bottom	8 lbs. (3.6 kg)
SC02NG	¾ Mini Size 2”H – Perforated Bottom	8 lbs. (3.6 kg)
SC03N	¾ Mini Size 3”H – Solid Bottom	10 lbs. (4.5 kg)
SC03NG	¾ Mini Size 3”H – Perforated Bottom	10 lbs. (4.5 kg)
SC04H	½ Size 4”H – Solid Bottom	12 lbs. (5.4 kg)
SC04HG	½ Size 4”H – Perforated Bottom	12 lbs. (5.4 kg)
SC05H	Half Size 5”H – Solid Bottom	12 lbs. (5.4 kg)
SC05HG	Half Size 5”H – Perforated Bottom	12 lbs. (5.4 kg)
SC06H	½ Size 6”H – Solid Bottom	14 lbs. (6.4 kg)
SC06HG	½ Size 6”H – Perforated Bottom	14 lbs. (6.4 kg)
SC08H	½ Size 8”H – Solid Bottom	16 lbs. (7.3 kg)

SC08HG	½ Size 8”H – Perforated Bottom	16 lbs. (7.3 kg)
SC04Q	¾ Size 4”H – Solid Bottom	18 lbs. (8.2 kg)
SC04QG	¾ Size 4”H – Perforated Bottom	18 lbs. (8.2 kg)
SC05Q	¾ Size 5”H – Solid Bottom	22 lbs. (10.0 kg)
SC05QG	¾ Size 5”H – Perforated Bottom	22 lbs. (10.0 kg)
SC06Q	¾ Size 6”H – Solid Bottom	22 lbs. (10.0 kg)
SC06QG	¾ Size 6”H – Perforated Bottom	22 lbs. (10.0 kg)
SC08Q	¾ Size 8”H – Solid Bottom	25 lbs. (11.3 kg)
SC08QG	¾ Size 8”H – Perforated Bottom	25 lbs. (11.3 kg)
SC04F	Full Size 4”H – Solid Bottom	25 lbs. (11.3 kg)
SC04FG	Full Size 4”H – Perforated Bottom	25 lbs. (11.3 kg)
SC05F	Full Size 5”H – Solid Bottom	25 lbs. (11.3 kg)
SC05FG	Full Size 5”H – Perforated Bottom	25 lbs. (11.3 kg)
SC06F	Full Size 6”H – Solid Bottom	25 lbs. (11.3 kg)
SC06FG	Full Size 6”H – Perforated Bottom	25 lbs. (11.3 kg)
SC08F	Full Size 8”H – Solid Bottom	25 lbs. (11.3 kg)
SC08FG	Full Size 8”H – Perforated Bottom	25 lbs. (11.3 kg)
SC04L	Long Size 4"H – Solid Bottom	30 lbs. (13.6 kg)
SC04LG	Long Size 4"H – Perforated Bottom	30 lbs. (13.6 kg)
SC06L	Long Size 6"H – Solid Bottom	30 lbs. (13.6 kg)
SC06LG	Long Size 6"H – Perforated Bottom	30 lbs. (13.6 kg)
SC08L	Long Size 8"H – Solid Bottom	30 lbs. (13.6 kg)
SC08LG	Long Size 8"H – Perforated Bottom	30 lbs. (13.6 kg)

Table 2. Recommended Load and Sizing for SteriTite® Containers for Table Top Sterilizers

Part Number	Description	Total weight load including container
SC02M	Mini Size 2”H – Solid Bottom	6 lbs. (2.7 kg)
SC02MG	Mini Size 2”H – Perforated Bottom	6 lbs. (2.7 kg)
SC03M	Mini Size 3”H – Solid Bottom	8 lbs. (3.6 kg)
SC03MG	Mini Size 3”H – Perforated Bottom	8 lbs. (3.6 kg)
SC04M	Mini Size 4”H – Solid Bottom	8 lbs. (3.6 kg)
SC04MG	Mini Size 4”H – Perforated Bottom	8 lbs. (3.6 kg)
SC02N	¾ Mini Size 2”H – Solid Bottom	8 lbs. (3.6 kg)
SC02NG	¾ Mini Size 2”H – Perforated Bottom	8 lbs. (3.6 kg)
SC03N	¾ Mini Size 3”H – Solid Bottom	10 lbs. (4.5 kg)
SC03NG	¾ Mini Size 3”H – Perforated Bottom	10 lbs. (4.5 kg)

Comparison with the predicate device:

The SteriTite® container system is the same SteriTite® container system previously cleared for pre-vacuum, gravity displacement, and IUSS steam sterilization.

All SteriTite containers are the same units as previously cleared, containing the same characteristics, such as knife edge fit between lid and base, anodized aluminum and passivated stainless-steel materials of construction, offset vent pattern, gasketed lids with latching mechanism, tamper evident features, and external labeling, seals and indicators. The SteriTite® sealed container in this submission is the same container previously cleared in the predicate submission. The subject device includes additional claims for extended maintenance of sterility, reduced dry time and table-top steam sterilization claims.

	Subject device (K173259)	Predicate (K022978)
Indications for Use:	The SteriTite® container system with MediTray® products is a rigid reusable sealed 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 a perforated base, perforated lid with filter retention plates, and disposable filters. Case Medical endorses a dry outcome for sterilization, transport, storage, and subsequent use. The SteriTite® container has been validated for prevacuum sterilization at 132°C for 4 minutes. with 3 stainless steel (3mm inner diameter × 400mm length) and 3 porous lumens (2mm inner diameter × 400mm length), and representative products of the MediTray line of accessories such as: 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, stacked trays, and mixed loads. Additionally, the SteriTite® container has been validated for prevacuum sterilization at 134°C for 4 minutes using tabletop autoclaves for metal instrument loads with 5 stainless steel lumen (2mm ID × 250mm length). The following claims have been validated for this device: • One (1) Year sterile shelf life/maintenance of sterility claim: • Reduced Dry Time Claim for Pre-Vacuum Steam Sterilization: SteriTite® containers previously cleared for terminal and IUSS (flash) steam sterilization may be used for storage and transport after steam sterilization with a reduced dry time. Dry loads will be achieved using a minimum of 5 minutes dry time when using perforated bottom units and a minimum of 8 minutes dry time when using solid bottom units. • Compatibility with Table Top Pre-Vacuum Steam Sterilization: SteriTite® containers previously cleared for steam sterilization may be used in small table top sterilizers with	The SteriTite containers with FlashTite valve plate(s) are intended to be used in conjunction with MediTray basic tray for the flash sterilization of one instrument or instrument set. The SteriTite container system with MediTray product are intended to be used to contain medical devices for steam sterilization. The full line of MediTray product is intended for complex customization in pre- Vacuum steam sterilization. MediTray basic trays are intended to be used in the sealed container for sterilization in steam pre-vacuum and gravity sterilization. MediTray products may be used separately for sterilization when wrapped in FDA cleared medical grade wrappers. The MediTray products include case/trays with lid and base, insert boxes, cassettes, trays, baskets, instrument racks, si1icone mats, brackets, posts, partitions.

	dynamic air removal. Container sizes are limited due to the small chamber of the table top sterilizer.	
Materials of construction	anodized aluminum stainless steel hardware silicone gaskets.	same
Device Design	• off set vent pattern • disposable filter in lid • interchangeable filter retention plates • recessed gasket	Same
Reusable	yes	yes
Patient contact	No direct patient contact	Same

Non Clinical Performance Data:

One (1) Year Shelf Life Claim

The SteriTite® container has been challenged under event related conditions in real time. An accelerated time study was conducted to demonstrate equivalence to a one-year shelf life. Subsequently, we verified these claims with a whole package aerosol microbial challenge performed in a qualified independent laboratory. The challenged containers were negative for growth.

One (1) year shelf life is claimed based on the following rationale and test data.

Rationale: Event related sterility maintenance is crucial for determining sterility maintenance of contents. Criteria, such as compromised filters, tampered seals, environmental conditions, and accidental opening of the device, will indicate whether the set needs to be reprocessed. Simulated handling events will indicate whether the package can maintain its' integrity when transported, rotated on shelves, and can withstand environmental contamination and stresses. In addition to handling events, the SteriTite container system has undergone real time shelf life studies in the past.

The following studies have been performed to simulate a one (1) year shelf life claim with whole package microbial challenge to validate the claim, and are now included in the IFU:

Time Study:

One (1) year Accelerated Shelf Life Test / Sterility Maintenance Study

Containers representative of SteriTite line of product were processed in steam sterilization followed be an aging study per ASTM guidelines. The outcome was verified by a Whole Package Microbial Aerosol Challenge conducted at a qualified independent laboratory in accordance with FDA guidance and available ASTM standards.

Reduced Dry Time

Case Medical endorses a dry outcome for sterilization, transport, storage, and subsequent use. The SteriTite container has successfully demonstrated dry loads using a shortened dry time of five (5) minutes in pre-vacuum steam sterilization, using paper filter and perforated bottom units. Eight (8) minutes was successfully demonstrated with solid bottom units and paper filters.

We conducted numerous shorter dry time studies in our laboratory using single and multiple units in the autoclave chamber using pre-vacuum steam sterilization cycles. Subsequently, an independent laboratory validated the outcome. The Reduced Dry Time Study was successfully conducted at a qualified independent laboratory in accordance with FDA guidance and available AAMI standards using perforated and solid base containers. No residual moisture was present after sterilization with dry times of 5 and 8 minutes respectively.

Conclusion: The successful Reduced Dry Time Validation Study indicates that the SteriTite® container system with paper (cellulosic) filter processed in pre-vacuum steam sterilization with a reduced dry time shows no moisture, resulting in dry loads that are safe for terminal sterilization and subsequent storage for later use.

Compatibility with Pre-Vacuum Table Top Steam Sterilization

The same SteriTite containers previously cleared for steam sterilization is compatible with table top dynamic air removal autoclaves. The Steam Sterilization Efficacy Validation (Lethality) Study of the SteriTite® sealed containers with contents of 4.4 lbs. including 2x250 mm rigid lumens, knurled and hinged devices in a half cycle of a table-top sterilizer was successfully conducted at a qualified independent laboratory in accordance with FDA guidance and available AAMI standards. The sterilization load contained two solid bottom containers (as a worst-case scenario), one on each shelf.

Conclusion: The SteriTite container System is compatible with steam sterilization including table top dynamic air removal (pre-vacuum sterilizers). The successful half cycle Steam Sterilization Efficacy (Lethality) Study in a table top sterilizer proves that the SteriTite container system effectively sterilizes instrumentation in Table Top steam sterilizers.

Conclusion:

Based on the performed nonclinical tests, the device is as safe, as effective, and performs as well as the legally marketed predicate device, K022978.