April 29, 2022

Case Medical, Inc.
Michael Polozani
Regulatory Affairs
50 West Street
Bloomfield, New Jersey 07003

Re: K212711
    Trade/Device Name: SteriTite Container System with MediTray Products
    Regulation Number: 21 CFR 880.6850
    Regulation Name: Sterilization Wrap
    Regulatory Class: Class II
    Product Code: KCT
    Dated: April 12, 2022
    Received: April 13, 2022

Dear Michael Polozani:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's

requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/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 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to 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,

for Clarence W. Murray, III, PhD
Acting Assistant Director
DHT4B: Division of Infection Control
    and Plastic Surgery 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)*
K212711

Device Name
SteriTite Container System 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. This container system is compatible for use with the following low temperature sterilizers and cycles identified below:

- STERIS V-Pro 60 (Flexible and Lumen cycle)
- STERIS V-Pro s2 (Flexible and Lumen cycle)
- STERIS V-Pro maX 2 (Lumen and Flexible cycle)
- STERIS V-Pro maX (Lumen and Flexible cycle)
- STERRAD 100NX (ALLCLEAR-DUO cycle)
- Sterizone VP4 (Cycle 1)

Refer to the specific Sterilizer user manual and vendor provided information regarding the processing of appropriate devices and device type. See the following pages for tables of compatible devices and description of the validated loads.

The following table (Table 1) identifies the validated lumen claims of the SteriTite container with MediTray parts in low temperature and pre-vacuum steam sterilizers:

Table 1. SteriTite Container System with MediTray Parts Lumen Claims:

Sterilizer	Cycle	Lumen Sterilization Claims (I.D. x Length)
STERIS V-Pro 60	Flexible	≥1mm x ≤990mm (Single or Dual Lumen)
STERIS V-Pro 60	Lumen	≥0.77mm x ≤527mm (Dual Channel)
STERIS V-Pro s2	Flexible	≥1mm x ≤990mm (Single or Dual Lumen)
STERIS V-Pro s2	Lumen	≥0.77mm x ≤527mm (Dual Channel)
STERIS V-Pro maX 2	Flexible	≥1mm x ≤1050mm (Single Lumen)
STERIS V-Pro maX 2	Lumen	≥0.77mm x ≤527mm (Dual Channel)
STERIS V-Pro maX	Flexible	≥1mm x ≤1050mm (Single Lumen)
STERIS V-Pro maX	Lumen	≥0.77mm x ≤527mm (Dual Channel)
STERRAD 100NX	DUO	≥1mm x ≤875mm (Single Lumen)
Sterizone VP4	Cycle 1	≥1.2mm x ≤1955mm (Flexible Lumens)
Sterizone VP4	Cycle 1	≥1.45mm x ≤3500mm (Flexible Lumens)
Steam	Pre-Vac	≥2mm x ≤400mm (Stainless Steel Lumen)
		≥1.2mm x ≤400mm (Flexible Lumen)

The following table (Table 2) displays the SteriTite part numbers and the sterilizers they are compatible with.

Table 2. SteriTite Container Compatibility with Low Temperature and Steam Sterilizers

V-Pro s2/60 Lumen Flex	V-Pro 1 Lumen Cycle	V-Pro maX/2 Lumen Flex	Sterizone VP4 Cycle 1	STERRAD 100NX DUO	STERRAD 100NX Standard Flex
SC02MG	SC02MG	SC02MG	SC02M(G)*	SC02MG	SC02MG
SC03MG	SC03MG	SC03MG	SC03M(G)*	SC03MG	SC03MG
SC04MG	SC02NG	SC04MG	SC04M(G)*	SC04MG	SC04MG
SC02NG	SC03NG	SC02NG	SC02N(G)*	SC02NG	SC02NG
SC03NG	SC04FG	SC03NG	SC03N(G)*	SC03NG	SC03NG
SC04NLG	SC05FG	SC04NLG	SC04NL(G)*	SC04NLG	SC04NLG
SC05NLG	SC06FG	SC05NLG	SC05NL(G)*	SC05NLG	SC05NLG
SC04HG	SC08FG	SC04HG	SC04H(G)*	SC04HG	SC04HG
SC05HG	SC04HG	SC05HG	SC05H(G)*	SC05HG	SC05HG
SC04QG	SC05HG	SC06HG	SC06H(G)*	SC06HG	SC06HG
SC05QG	SC06HG	SC08HG	SC08H(G)*	SC08HG	SC08HG
SC04FG	SC08HG	SC04QG	SC04Q(G)*	SC04QG	SC04QG
	SC04QG	SC05QG	SC05Q(G)*	SC05QG	SC05QG
	SC05QG	SC06QG	SC06Q(G)*	SC04FG	SC06QG
	SC06QG	SC08QG	SC08Q(G)*	SC05FG	SC08QG
	SC08QG	SC04FG	SC04F(G)*	SC04LG	SC04FG
	SC04LG	SC05FG	SC04L(G)*	SC05WG	SC05FG
	SC06LG	SC06FG	SC06L(G)*		SC06FG
	SC08LG	SC08FG	SC08L(G)*		SC08FG
	SC05WG	SC04LG			SC04LG
		SC06LG			SC06LG
		SC08LG			SC08LG
		SC05WG			SC05WG

*Please note that the SteriTite perforated bottom and solid bottom containers are compatible with the Sterizone VP4 Sterilizer.

Table 2 (Continued). SteriTite Container Compatibility with Low Temperature and Steam Sterilizers

STERRAD 100S/200 Standard	NX Standard Advanced	Steam Pre-Vac Gravity IUSS
SC02MG	SC02MG	SC02MG
SC03MG	SC03MG	SC03MG
SC04MG	SC04MG	SC04MG
SC02NG	SC02NG	SC02NG
SC03NG	SC03NG	SC03NG
SC04NLG	SC04HG	SC04NLG
SC05NLG	SC05HG	SC05NLG
SC04HG	SC04QG	SC04HG
SC05HG	SC05QG	SC05HG
SC06HG	SC04FG	SC06HG
SC08HG		SC08HG
SC04QG		SC04QG
SC05QG		SC05QG
SC06QG		SC06QG
SC08QG		SC08QG
SC04FG		SC04FG
SC05FG		SC05FG
SC06FG		SC06FG
SC08FG		SC08FG
		SC04LG
		SC06LG
		SC08LG
		SC05WG

The following table (Table 3) identifies which MediTray products are compatible with low temperature sterilizers and steam sterilization:

Table 3. MediTray Products Sterilizer Compatibility Table

MediTray Product	V-Pro maX/2	V-Pro 1	V-Pro s2/60	STERRAD 100NX	STERRAD 100s/200	STERRAD NX	STERIZONE VP4	STEAM
Baskets	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Trays	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Insert Boxes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Metal Brackets	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Metal Partitions	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Posts	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Silicone Brackets	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Racks	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Stringers	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes

The following table (Table 4) identifies which SteriTite accessories are compatible with low temperature sterilizers and steam sterilization:

Table 4. SteriTite Accessories Sterilizer Compatibility Table

SteriTite Accessories	V-Pro maX/2	V-Pro 1	V-Pro s2/60	STERRAD 100NX	STERRAD 100s	STERRAD NX	STERIZONE VP4	Steam
Baskets	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Trays	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Insert Boxes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Metal Brackets	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Metal Partitions	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Posts	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Silicone Brackets	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Racks	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Stringers	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes

The following tables (5-11) identify the sterilizer maximum load weight recommendations with the SteriTite containers:

Table 5. SteriTite Container in V-Pro s2 and V-Pro 60 Maximum Load Weight Recommendations Including Weight of Container

Part Number	Total Load Weight in V-Pro s2/60 Lumen Cycle	Total Load Weight in V-Pro s2/60 Flexible Cycle
SC02MG	25 lbs	11 lbs
SC03MG	25 lbs	11 lbs
SC04MG	25 lbs	11 lbs
SC02NG	25 lbs	11 lbs
SC03NG	25 lbs	11 lbs
SC04NLG	25 lbs	11 lbs
SC05NLG	25 lbs	11 lbs
SC04HG	25 lbs	11 lbs
SC05HG	25 lbs	11 lbs
SC04QG	25 lbs	11 lbs
SC05QG	25 lbs	11 lbs
SC04FG	25 lbs	11 lbs

Table 6. SteriTite Container in STERRAD NX Maximum Load Weight Recommendations Including Weight of Container

Part Number	Total Load Weight in NX Standard Cycle	Total Load Weight in NX Advanced Cycle
SC02MG	10.7 lbs	10.7 lbs
SC03MG	10.7 lbs	10.7 lbs
SC04MG	10.7 lbs	10.7 lbs
SC02NG	10.7 lbs	10.7 lbs
SC03NG	10.7 lbs	10.7 lbs
SC04HG	10.7 lbs	10.7 lbs
SC05HG	10.7 lbs	10.7 lbs
SC04QG	10.7 lbs	10.7 lbs
SC05QG	10.7 lbs	10.7 lbs
SC04FG	10.7 lbs	10.7 lbs

Table 7. SteriTite Container in V-Pro 1 Maximum Load Weight Recommendations Including Weight of Container

Part Number	Total Load Weight in V-Pro 1 Lumen Cycle
SC02MG	19.65 lbs
SC03MG	19.65 lbs
SC02NG	19.65 lbs
SC03NG	19.65 lbs
SC04FG	19.65 lbs
SC05FG	19.65 lbs
SC06FG	19.65 lbs
SC08FG	19.65 lbs
SC04HG	19.65 lbs
SC05HG	19.65 lbs
SC06HG	19.65 lbs
SC08HG	19.65 lbs
SC04QG	19.65 lbs
SC05QG	19.65 lbs
SC06QG	19.65 lbs
SC08QG	19.65 lbs
SC04LG	19.65 lbs
SC06LG	19.65 lbs
SC08LG	19.65 lbs
SC05WG	19.65 lbs

Table 8. SteriTite Container in STERRAD 100s/200 Maximum Load Weight Recommendations Including Weight of Container

Part Number	Total Load Weight in the STERRAD 100s Standard Cycle
SC02MG	22 lbs
SC03MG	22 lbs
SC04MG	22 lbs
SC02NG	22 lbs
SC03NG	22 lbs
SC04NLG	22 lbs
SC05NLG	22 lbs
SC04HG	22 lbs
SC05HG	22 lbs
SC06HG	22 lbs
SC08HG	22 lbs
SC04QG	22 lbs
SC05QG	22 lbs
SC06QG	22 lbs
SC08QG	22 lbs
SC04FG	22 lbs
SC05FG	22 lbs
SC06FG	22 lbs
SC08FG	22 lbs

Table 9. SteriTite Container in 100NX Maximum Load Weight Recommendations Including Weight of Container.

Part Number	Total Load Weight in 100NX Standard Cycle	Total Load Weight in 100NX Flex Cycle	Total Load Weight in 100NX DUO Cycle
SC02MG	21.4 lbs	21.4 lbs	13.2 lbs
SC03MG	21.4 lbs	21.4 lbs	13.2 lbs
SC04MG	21.4 lbs	21.4 lbs	13.2 lbs
SC02NG	21.4 lbs	21.4 lbs	13.2 lbs
SC03NG	21.4 lbs	21.4 lbs	13.2 lbs
SC04NLG	21.4 lbs	21.4 lbs	13.2 lbs
SC05NLG	21.4 lbs	21.4 lbs	13.2 lbs
SC04HG	21.4 lbs	21.4 lbs	13.2 lbs
SC05HG	21.4 lbs	21.4 lbs	13.2 lbs
SC06HG	21.4 lbs	21.4 lbs	13.2 lbs
SC08HG	21.4 lbs	21.4 lbs	13.2 lbs
SC04QG	21.4 lbs	21.4 lbs	13.2 lbs
SC05QG	21.4 lbs	21.4 lbs	13.2 lbs
SC06QG	21.4 lbs	21.4 lbs	NA
SC08QG	21.4 lbs	21.4 lbs	NA
SC04FG	21.4 lbs	21.4 lbs	13.2 lbs
SC05FG	21.4 lbs	21.4 lbs	13.2 lbs
SC06FG	21.4 lbs	21.4 lbs	NA
SC08FG	21.4 lbs	21.4 lbs	NA
SC04LG	21.4 lbs	21.4 lbs	13.2 lbs
SC06LG	21.4 lbs	21.4 lbs	NA
SC08LG	21.4 lbs	21.4 lbs	NA
SC05WG	21.4 lbs	21.4 lbs	13.2 lbs

Table 10. SteriTite Container in V-Pro maX/maX 2 Maximum Load Weight Recommendations 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
SC02MG	19.65 lbs	24 lbs	50 lbs
SC03MG	19.65 lbs	24 lbs	50 lbs
SC04MG	19.65 lbs	24 lbs	50 lbs
SC02NG	19.65 lbs	24 lbs	50 lbs
SC03NG	19.65 lbs	24 lbs	50 lbs
SC04NLG	19.65 lbs	24 lbs	50 lbs
SC05NLG	19.65 lbs	24 lbs	50 lbs
SC04HG	19.65 lbs	24 lbs	50 lbs
SC05HG	19.65 lbs	24 lbs	50 lbs
SC06HG	19.65 lbs	24 lbs	50 lbs
SC08HG	19.65 lbs	24 lbs	50 lbs
SC04QG	19.65 lbs	24 lbs	50 lbs
SC05QG	19.65 lbs	24 lbs	50 lbs
SC06QG	19.65 lbs	24 lbs	50 lbs
SC08QG	19.65 lbs	24 lbs	50 lbs
SC04FG	19.65 lbs	24 lbs	50 lbs
SC05FG	19.65 lbs	24 lbs	50 lbs
SC06FG	19.65 lbs	24 lbs	50 lbs
SC08FG	19.65 lbs	24 lbs	50 lbs
SC04LG	19.65 lbs	24 lbs	50 lbs
SC06LG	19.65 lbs	24 lbs	50 lbs
SC08LG	19.65 lbs	24 lbs	50 lbs
SC05WG	19.65 lbs	24 lbs	50 lbs

Table 11. SteriTite Container in Steam Sterilization/IUSS Maximum Load Weight Recommendations Including Weight of Container.

Part Number	Total Load Weight in Steam Sterilization Pre-Vacuum Cycle	Total Load Weight in Steam Sterilization Gravity Cycle
SC02MG	35 lbs	35 lbs
SC03MG	35 lbs	35 lbs
SC04MG	35 lbs	35 lbs
SC02NG	35 lbs	35 lbs
SC03NG	35 lbs	35 lbs
SC04NLG	35 lbs	35 lbs
SC05NLG	35 lbs	35 lbs
SC04HG	35 lbs	35 lbs
SC05HG	35 lbs	35 lbs
SC06HG	35 lbs	35 lbs
SC08HG	35 lbs	35 lbs
SC04QG	35 lbs	35 lbs
SC05QG	35 lbs	35 lbs
SC06QG	35 lbs	35 lbs
SC08QG	35 lbs	35 lbs
SC04FG	35 lbs	35 lbs
SC05FG	35 lbs	35 lbs
SC06FG	35 lbs	35 lbs
SC08FG	35 lbs	35 lbs
SC04LG	35lbs	35lbs
SC06LG	35lbs	35lbs
SC08LG	35lbs	35lbs
SC05WG	35lbs	35lbs

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.

510K Summary

SteriTite Container System with MediTray Products

Date Prepared :	04/28/2022
Company Name :	Case Medical, Inc 50 West Street Bloomfield NJ 07003
Contact:	Michael Polozani
Email	MPolozani@casemed.com
Office	201-313-1999 x 633
Fax	201-373-9090
Trade Name	SteriTite Container System with MediTray Products
Common Name	Sterilization Wrap Containers, Trays, Cassettes, and Other Accessories
Class of Device	Class II
Product Code	KCT
Regulation	21CFR880.6850
Review Panel	General Hospital
Establishment Registration Number	2248608
Predicate Device	K173259-SteriTite Rigid Container System with MediTray Products
Description of 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 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**.**

Indications for Use

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. This container system is compatible for use with the following low temperature sterilizers and cycles identified below:

- V-Pro 60 (Flexible and Lumen cycle).
- V-Pro s2 (Flexible and Lumen cycle).
- V-Pro maX 2 (Flexible and Lumen cycle)
- V-Pro maX (Flexible and Lumen cycle)
- STERRAD 100NX (ALLCLEAR-DUO Cycle)
- Sterizone VP4 (Cycle 1)

The SteriTite container with MediTray accessories has the following validated lumen claims in low temperature and pre-vacuum steam sterilization:

The following table (Table 1) identifies the lumen claims of the SteriTite container with MediTray parts in low temperature and steam sterilizers:

Table 1. SteriTite Container System with MediTray Parts Lumen Claims

Sterilizer	Cycle	Lumen Sterilization Claims (I.D. x Length)	Validated Lumen Characteristics
STERIS V-Pro 60	Flexible	≥1mm x ≤990mm	Single or Dual Lumen
	Lumen	≥0.77mm x ≤527mm	Dual Channel
STERIS V-Pro s2	Flexible	≥1mm x ≤990mm	Single or Dual Lumen
	Lumen	≥0.77mm x ≤527mm	Dual Channel
STERIS V-Pro maX 2	Flexible	≥1mm x <1050mm	Single Lumen
STERIS V-Pro maX	Flexible	≥1mm x <1050mm	Single Lumen
	Lumen	≥0.77mm x ≤527mm	Dual Channel
STERRAD 100NX	DUO	≥1mm x ≤875mm	Single Lumen
Sterizone VP4	Cycle 1	≥1.2mm x ≤1955mm	Flexible Lumens
		≥1.45mm x ≤3500mm	Flexible Lumens
Steam	Pre-Vac	≥2mm x ≤400mm	Stainless Steel Lumen
		≥1.2mm x ≤400mm	Flexible Lumen

The following table (Table 2) displays the SteriTite part numbers and the sterilizers they are compatible with:

Table 2. SteriTite Container Compatibility with Low Temperature and Steam Sterilizers

V-Pro s2/60 Lumen Flex	V-Pro 1 Lumen	V-Pro maX/maX2 Lumen Flex	Sterizone VP4 Cycle 1	STERRAD 100NX DUO	STERRAD 100NX Standard Flex	STERRAD 100S/200 Standard	NX Advanced Standard	Steam Pre-vac Gravity IUSS
SC02MG	SC02MG	SC02MG	SC02M(G)*	SC02MG	SC02MG	SC02MG	SC02MG	SC02MG
SC03MG	SC03MG	SC03MG	SC03M(G)*	SC03MG	SC03MG	SC03MG	SC03MG	SC03MG
SC04MG	SC02NG	SC04MG	SC04M(G)*	SC04MG	SC04MG	SC04MG	SC04MG	SC04MG
SC02NG	SC03NG	SC02NG	SC02N(G)*	SC02NG	SC02NG	SC02NG	SC02NG	SC02NG
SC03NG	SC04FG	SC03NG	SC03N(G)*	SC03NG	SC03NG	SC03NG	SC03NG	SC03NG
SC04NLG	SC05FG	SC04NLG	SC04NL(G)*	SC04NLG	SC04NLG	SC04NLG	SC04HG	SC04NLG
SC05NLG	SC06FG	SC05NLG	SC05NL(G)*	SC05NLG	SC05NLG	SC05NLG	SC05HG	SC05NLG
SC04HG	SC08FG	SC04HG	SC04H(G)*	SC04HG	SC04HG	SC04HG	SC04QG	SC04HG
SC05HG	SC04HG	SC05HG	SC05H(G)*	SC05HG	SC05HG	SC05HG	SC05QG	SC05HG
SC04QG	SC05HG	SC06HG	SC06H(G)*	SC06HG	SC06HG	SC06HG	SC04FG	SC06HG
SC05QG	SC06HG	SC08HG	SC08H(G)*	SC08HG	SC08HG	SC08HG		SC08HG
SC04FG	SC08HG	SC04QG	SC04Q(G)*	SC04QG	SC04QG	SC04QG		SC04QG
	SC04QG	SC05QG	SC05Q(G)*	SC05QG	SC05QG	SC05QG		SC05QG
	SC05QG	SC06QG	SC06Q(G)*	SC04FG	SC06QG	SC06QG		SC06QG
	SC06QG	SC08QG	SC08Q(G)*	SC05FG	SC08QG	SC08QG		SC08QG
	SC08QG	SC04FG	SC04F(G)*	SC04LG	SC04FG	SC04FG		SC04FG
	SC04FG	SC05FG	SC04L(G)*	SC05WG	SC05FG	SC05FG		SC05FG
	SC04LG	SC06FG	SC06L(G)*		SC06FG	SC06FG		SC06FG
	SC06LG	SC08FG	SC08L(G)*		SC08FG	SC08FG		SC08FG
	SC08LG	SC04LG			SC04LG			SC04LG
	SC05WG	SC06LG			SC06LG			SC06LG
		SC08LG			SC08LG			SC08LG
		SC05WG			SC05WG			SC05WG

Please note that the SteriTite perforated bottom and solid bottom containers are compatible with the Sterizone VP4 Sterilizer.

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

Table 3. MediTray Products Sterilizer Compatibility Table

MediTray Product	V-Pro maX/2	V-Pro 1	V-Pro s2/60	STERRAD 100NX	STERRAD 100S/200	STERRAD NX	STERIZONE VP4	Steam
Baskets	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Trays	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Insert Boxes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Metal Brackets	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Metal Partitions	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Posts	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Silicone Brackets	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Racks	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Stringers	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes

The following table identifies which SteriTite accessories are compatible with low temperature sterilizers and steam sterilization:

Table 4. SteriTite Accessories Sterilizer Compatibility Table

SteriTite Accessories	V-Pro maX/2	V-Pro 1	V-Pro s2/60	STERRAD 100NX	STERRAD 100S	STERRAD NX	STERIZONE VP4	Steam
SCF02 Round filter	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
SCFM02 Rectangular filter	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
SCS01W Tamper Evident Seals	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
SCLH2O23 Load Card Large	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
SCLH2O24 Load Card Small	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes

The following tables (5-11) identify the sterilizer maximum load weight recommendations with the SteriTite containers:

Table 5. SteriTite Container in V-Pro s2 and V-Pro 60 Maximum Load Weight Recommendations Including Weight of Container

Part Number	Total Load Weight in V-Pro s2/60 Lumen Cycle	Total Load Weight in V-Pro s2/60 Flexible Cycle
SC02MG	25lbs	11lbs
SC03MG	25lbs	11lbs
SC04MG	25lbs	11lbs
SC02NG	25lbs	11lbs
SC03NG	25lbs	11lbs
SC04NLG	25lbs	11lbs
SC05NLG	25lbs	11lbs
SC04HG	25lbs	11lbs
SC05HG	25lbs	11lbs
SC04QG	25lbs	11lbs
SC05QG	25lbs	11lbs
SC04FG	25lbs	11lbs

Table 6. SteriTite Container in STERRAD NX Maximum Load Weight Recommendations Including Weight of Container

Part Number	Total Load Weight in NX Standard Cycle	Total Load Weight in NX Advanced Cycle
SC02MG	10.7lbs	10.7lbs
SC03MG	10.7lbs	10.7lbs
SC04MG	10.7lbs	10.7lbs
SC02NG	10.7lbs	10.7lbs
SC03NG	10.7lbs	10.7lbs
SC04HG	10.7lbs	10.7lbs
SC05HG	10.7lbs	10.7lbs
SC04QG	10.7lbs	10.7lbs
SC05QG	10.7lbs	10.7lbs
SC04FG	10.7lbs	10.7lbs

Table 7. SteriTite Container in V-Pro 1 Maximum Load Weight Recommendations Including Weight of Container

Part Number	Total Load Weight in V-Pro 1 Lumen Cycle
SC02MG	19.65lbs
SC03MG	19.65lbs
SC02NG	19.65lbs
SC03NG	19.65lbs
SC04FG	19.65lbs
SC05FG	19.65lbs
SC06FG	19.65lbs
SC08FG	19.65lbs
SC04HG	19.65lbs
SC05HG	19.65lbs
SC06HG	19.65lbs
SC08HG	19.65lbs
SC04QG	19.65lbs
SC05QG	19.65lbs
SC06QG	19.65lbs
SC08QG	19.65lbs
SC04LG	19.65lbs
SC06LG	19.65lbs
SC08LG	19.65lbs
SC05WG	19.65lbs

Table 8. SteriTite Container in STERRAD 100s/200 Maximum Load Weight Recommendations Including Weight of Container

Part Number	Total Load Weight in the STERRAD 100s/200 Standard Cycle
SC02MG	22lbs
SC03MG	22lbs
SC04MG	22lbs
SC02NG	22lbs
SC03NG	22lbs
SC04NLG	22lbs
SC05NLG	22lbs
SC04HG	22lbs
SC05HG	22lbs
SC06HG	22lbs
SC08HG	22lbs
SC04QG	22lbs
SC05QG	22lbs
SC06QG	22lbs
SC08QG	22lbs
SC04FG	22lbs
SC05FG	22lbs
SC06FG	22lbs
SC08FG	22lbs

Table 9. SteriTite Container in 100NX Maximum Load Weight Recommendations Including Weight of Container

Part Number	Total Load Weight in 100NX Standard Cycle	Total Load Weight in 100NX Flex Cycle	Total Load Weight in 100NX DUO Cycle
SC02MG	21.4lbs	21.4lbs	13.2lbs
SC03MG	21.4lbs	21.4lbs	13.2lbs
SC04MG	21.4lbs	21.4lbs	13.2lbs
SC02NG	21.4lbs	21.4lbs	13.2lbs
SC03NG	21.4lbs	21.4lbs	13.2lbs
SC04NLG	21.4lbs	21.4lbs	13.2lbs
SC05NLG	21.4lbs	21.4lbs	13.2lbs
SC04HG	21.4lbs	21.4lbs	13.2lbs
SC05HG	21.4lbs	21.4lbs	13.2lbs
SC06HG	21.4lbs	21.4lbs	13.2lbs
SC08HG	21.4lbs	21.4lbs	13.2lbs
SC04QG	21.4lbs	21.4lbs	13.2lbs
SC05QG	21.4lbs	21.4lbs	13.2lbs
SC06QG	21.4lbs	21.4lbs	NA
SC08QG	21.4lbs	21.4lbs	NA
SC04FG	21.4lbs	21.4lbs	13.2lbs
SC05FG	21.4lbs	21.4lbs	13.2lbs
SC06FG	21.4lbs	21.4lbs	NA
SC08FG	21.4lbs	21.4lbs	NA
SC04LG	21.4lbs	21.4lbs	13.2lbs
SC06LG	21.4lbs	21.4lbs	NA
SC08LG	21.4lbs	21.4lbs	NA
SC05WG	21.4lbs	21.4lbs	13.2lbs

Table 10. SteriTite Container in V-Pro maX/maX 2
Maximum Load Weight Recommendations
Including Weight of Container

Part Number	Total Load Weight in V-Pro maX/maX2 Lumen Cycle	Total Load Weight in V-Pro maX/maX2 Flex Cycle	Total Load Weight in V-Pro maX/maX2 Non-Lumen Cycle
SC02MG	19.65lbs	24lbs	50lbs
SC03MG	19.65lbs	24lbs	50lbs
SC04MG	19.65lbs	24lbs	50lbs
SC02NG	19.65lbs	24lbs	50lbs
SC03NG	19.65lbs	24lbs	50lbs
SC04NLG	19.65lbs	24lbs	50lbs
SC05NLG	19.65lbs	24lbs	50lbs
SC04HG	19.65lbs	24lbs	50lbs
SC05HG	19.65lbs	24lbs	50lbs
SC06HG	19.65lbs	24lbs	50lbs
SC08HG	19.65lbs	24lbs	50lbs
SC04QG	19.65lbs	24lbs	50lbs
SC05QG	19.65lbs	24lbs	50lbs
SC06QG	19.65lbs	24lbs	50lbs
SC08QG	19.65lbs	24lbs	50lbs
SC04FG	19.65lbs	24lbs	50lbs
SC05FG	19.65lbs	24lbs	50lbs
SC06FG	19.65lbs	24lbs	50lbs
SC08FG	19.65lbs	24lbs	50lbs
SC04LG	19.65lbs	24lbs	50lbs
SC06LG	19.65lbs	24lbs	50lbs
SC08LG	19.65lbs	24lbs	50lbs
SC05WG	19.65lbs	24lbs	50lbs

Table 11. SteriTite Container in Steam Sterilization/IUSS
Maximum Load Weight Recommendations
Including Weight of Container

Part Number	Total Load Weight in Steam Sterilization Pre-Vacuum Cycle	Total Load Weight in Steam Sterilization Gravity Cycle
SC02MG	35lbs	35lbs
SC03MG	35lbs	35lbs
SC04MG	35lbs	35lbs
SC02NG	35lbs	35lbs
SC03NG	35lbs	35lbs
SC04NLG	35lbs	35lbs
SC05NLG	35lbs	35lbs
SC04HG	35lbs	35lbs
SC05HG	35lbs	35lbs
SC06HG	35lbs	35lbs
SC08HG	35lbs	35lbs
SC04QG	35lbs	35lbs
SC05QG	35lbs	35lbs
SC06QG	35lbs	35lbs
SC08QG	35lbs	35lbs
SC04FG	35lbs	35lbs
SC05FG	35lbs	35lbs
SC06FG	35lbs	35lbs
SC08FG	35lbs	35lbs
SC04LG	35lbs	35lbs
SC06LG	35lbs	35lbs
SC08LG	35lbs	35lbs
SC05WG	35lbs	35lbs

Technological Characteristics Comparison

All functional and design characteristics are the same as the predicate previously cleared and show effective performance characteristics. The SteriTite container system is the same container system previously cleared and demonstrated the same technical and performance characteristics previously. Sterilization efficacy testing has been conducted to support new indications.

Summary of 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 ST79.

Based on the testing performed on the SteriTite container and MediTray parts, the device has demonstrated compatibility with the sterilizers indicated above. Results are summarized in Table 12.

Table 12: Summary of Non-Clinical Performance Testing

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 bacterial spores.	Pass
Biocompatibility	ANSI AAMI ISO 10993-1	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 compatibile with the intended sterilization cycles	Pass
Simulated Use Testing / Sterilization Efficacy	ANSI AAMI ISO 14937:2009/(R)2013	Testing was completed to demonstrate sterilization efficacy of the subject device for processing of medical devices with the indicated claims using the identified sterilization processes.	Pass

Conclusion

The conclusion drawn from the nonclinical tests demonstrates that the subject device in 510(k) submission K212711, the 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 K173259.