June 3, 2026

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

Re: K252854
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: May 4, 2026
Received: May 4, 2026

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 Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13484 clause 8.3 (Nonconforming product), and ISO 13485 clause 8.5 (Corrective and preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 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 Management System Regulation (QMSR) (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

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

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

STEPHEN A. ANISKO -S

Digitally signed by STEPHEN A. ANISKO -S
Date: 2026.06.03 13:05:32 -04'00'

Stephen Anisko
Acting Assistant Director
DHT4C: Division of Infection Control Devices
OHT4: Office of Surgical and Infection Control Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

Indications for Use

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

510(k) Number *(if known)*
K252854

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 devices until it is used.

The perforated bottom container configuration is compatible for use with the following steam sterilization cycles:

Steam Cycle with Steam Flush Pressure Pulses (SFPP):
-At 132°C for 4 minutes with a 30-minute dry time
-At 135°C for 3 minutes with a 30-minute dry time

Note: The validation studies were performed using a 4 SFPP cycle with a validation load consisting of unwrapped metal items with a total weight of 25 lbs. (including the SteriTite container).

In addition, the SteriTite container, also available with a solid bottom, is compatible with low-temperature sterilizers, and is compatible with the following sterilizers and cycles identified below:

- SteriTite solid bottom Container: STERRAD 100NX - Express Cycle (surface sterilization of medical devices only; no lumens).

  Note: The validation studies were performed using a validation load consisting of a da Vinci X/Xi 8mm Endoscope with a total weight of 22.4 lbs. (including the SteriTite container).

- SteriTite solid bottom Container: STERRAD 100NX - DUO Cycle (surface sterilization of medical devices only; no lumens).

  Note: The validation studies were performed using a validation load consisting of non-lumened devices with a total weight of 13.2 lbs. (including the SteriTite container).

  Refer to the specific Sterilizer user manual for information regarding the processing of appropriate devices and device types. See labeling for tables of compatible devices and maximum load weight recommendations including the weight of the sterilization container.

The following tables (Table 1 and Table 2) display the SteriTite part numbers and the sterilizers they are compatible with:

Table 1. SteriTite Perforated Bottom Container Compatibility with SFPP and Pre vacuum Steam Sterilizers.

Part Number	Description	SFPP	Gravity Steam
SC02MG	2” High Mini-Size w/ Perforated Base	Yes	Yes
SC03MG	3” High Mini-Size w/ Perforated Base	Yes	Yes
SC04MG	4” High Mini-Size w/ Perforated Base	Yes	Yes
SC02NG	2” High Narrow-Size w/ Perforated Base	Yes	Yes
SC03NG	3” High Narrow-Size w/ Perforated Base	Yes	Yes
SC03NLG	3” High Narrow Long-Size w/ Perforated Base	N/A	Yes
SC04NLG	4” High Narrow Long-Size w/ Perforated Base	N/A	Yes
SC05NLG	5” High Narrow Long -Size w/ Perforated Base	N/A	Yes
SC04HG	4” High Half-Size w/ Perforated Base	Yes	Yes
SC05HG	5” High Half-size w/ Perforated Base	Yes	Yes
SC06HG	6” High Half-Size w/ Perforated Base	Yes	Yes
SC08HG	8” High Half-Size w/ Perforated Base	N/A	Yes
SC04QG	4” High 3/4 Size w/ Perforated Base	Yes	Yes
SC05QG	5” High 3/4 Size w/ Perforated Base	Yes	Yes
SC06QG	6” High 3/4 Size w/ Perforated Base	Yes	Yes
SC08QG	8” High 3/4 Size w/ Perforated Base	N/A	Yes
SC04FG	4” High Full-size w/ Perforated Base	Yes	Yes
SC05FG	5” High Full-size w/ Perforated Base	Yes	Yes
SC06FG	6” High Full-size w/ Perforated Base	Yes	Yes
SC08FG	8” High Full-size w/ Perforated Base	N/A	Yes
SC04LG	4” High Long-size w/ Perforated Base	N/A	Yes
SC06LG	6” High Long-size w/ Perforated Base	N/A	Yes
SC08LG	8” High Long-size w/ Perforated Base	N/A	Yes
SC05WG	5” High Wide Size w/ Perforated Base	N/A	Yes

Note: Perforated bottom containers with part numbers with suffix (G) may be used in any sterilization modality. SteriTite containers with solid bottom may be used in pre-vacuum steam sterilization as well as low temperature modalities.
N/A notes that the specified container does not fit into the sterilizer chamber because of length or width.

Table 2. SteriTite Solid Bottom Container Compatibility with STERRAD 100NX and Steris V-Pro sterilizers

Part Number	Description	STERRAD 100NX	V-Pro s2/60	V-Pro maX/maX2
SC02M	2” High Mini-Size w/ Solid Base	Yes	Yes	Yes
SCO3M	3” High Mini-Size w/ Solid Base	Yes	Yes	Yes
SCO4M	4” High Mini-Size w/ Solid Base	Yes	Yes	Yes
SC02N	2” High Narrow-Size w/ Solid Base	Yes	Yes	Yes
SC03N	3” High Narrow-Size w/ Solid Base	Yes	Yes	Yes
SC03NL	3” High Narrow Long-Size w/ Solid Base	Yes	Yes	Yes
SC04NL	4” High Narrow Long-Size w/ Solid Base	Yes	Yes	Yes
SC05NL	5” High Narrow Long -Size w/ Solid Base	Yes	Yes	Yes
SC04H	4” High Half-Size w/ Solid Base	Yes	Yes	Yes
SC05H	5” High Half-size w/ Solid Base	Yes	Yes	Yes
SC06H	6” High Half-Size w/ Solid Base	Yes	Yes	Yes
SC08H	8” High Half-Size w/ Solid Base	Yes	Yes	Yes
SC04Q	4” High 3/4 Size w/ Solid Base	Yes	Yes	Yes
SC05Q	5” High 3/4 Size w/ Solid Base	Yes	Yes	Yes
SC06Q	6” High 3/4 Size w/ Solid Base	Yes	Yes	Yes
SC08Q	8” High 3/4 Size w/ Solid Base	Yes	Yes	Yes
SC04F	4” High Full-size w/ Solid Base	Yes	Yes	Yes
SC05F	5” High Full-size w/ Solid Base	Yes	Yes	Yes
SC06F	6” High Full-size w/ Solid Base	Yes	Yes	Yes
SC08F	8” High Full-size w/ Solid Base	Yes	Yes	Yes
SC04L	4” High Long-size w/ Solid Base	Yes	N/A	Yes
SC06L	6” High Long-size w/ Solid Base	Yes	N/A	Yes
SC08L	8” High Long-size w/ Solid Base	Yes	N/A	Yes
SC05W	5” High Wide Size w/ Solid Base	Yes	N/A	Yes

Note: Perforated bottom containers with part numbers with suffix (G) may be used in any sterilization modality. SteriTite containers with solid bottom may be used in pre-vacuum steam sterilization as well as low temperature modalities such as EtO, V-Pro, and in STERRAD sterilizers for surface sterilization have no G as a suffix in the part number.
N/A notates that the specified container does not fit into the sterilizer chamber because of length or width.

Table 3. SteriTite Container maximum load weight in Steam Sterilization

Part Number	Total Load Weight in Pre-Vacuum Cycle	Total Load Weight in Gravity Cycle	Total Load Weight in SFPP
SC02M(G)	35lbs	35lbs	25lbs
SC03M(G)	35lbs	35lbs	25lbs
SC04M(G)	35lbs	35lbs	25lbs
SC02N(G)	35lbs	35lbs	25lbs
SC03N(G)	35lbs	35lbs	25lbs
SC03NL(G)	35lbs	35lbs	N/A
SC04NL(G)	35lbs	35lbs	N/A
SC05NL(G)	35lbs	35lbs	N/A
SC04H(G)	35lbs	35lbs	25lbs
SC05H(G)	35lbs	35lbs	25lbs
SC06H(G)	35lbs	35lbs	25lbs
SC08H(G)	35lbs	35lbs	N/A
SC04Q(G)	35lbs	35lbs	25lbs
SC05Q(G)	35lbs	35lbs	25lbs
SC06Q(G)	35lbs	35lbs	25lbs
SC08Q(G)	35lbs	35lbs	N/A
SC04F(G)	35lbs	35lbs	25lbs
SC05F(G)	35lbs	35lbs	25lbs
SC06F(G)	35lbs	35lbs	25lbs
SC08F(G)	35lbs	35lbs	N/A
SC04L(G)	35lbs	35lbs	N/A
SC06L(G)	35lbs	35lbs	N/A
SC08L(G)	35lbs	35lbs	N/A
SC05W(G)	35lbs	35lbs	N/A

N/A notes that the specified container does not fit into the sterilizer chamber because of length or width.

Table 4. SteriTite Container in 100NX Maximum Load Weight

Part Number	Total Load Weight in 100NX Standard Cycle	Total Load Weight in 100NX Flexible Cycle	Total Load Weight in 100NX DUO Cycle	Total Load Weight in 100NX Express Cycle
SC02M(G)	21.4 lbs	21.4 lbs	13.2 lbs	22.4 lbs
SC03M(G)	21.4 lbs	21.4 lbs	13.2 lbs	22.4 lbs
SC04M(G)	21.4 lbs	21.4 lbs	13.2 lbs	22.4 lbs
SC02N(G)	21.4 lbs	21.4 lbs	13.2 lbs	22.4 lbs
SC03N(G)	21.4 lbs	21.4 lbs	13.2 lbs	22.4 lbs
SC03NL(G)	21.4 lbs	21.4 lbs	13.2 lbs	22.4 lbs
SC04NL(G)	21.4 lbs	21.4 lbs	13.2 lbs	22.4 lbs
SC05NL(G)	21.4 lbs	21.4 lbs	13.2 lbs	22.4 lbs
SC04H(G)	21.4 lbs	21.4 lbs	13.2 lbs	22.4 lbs
SC05H(G)	21.4 lbs	21.4 lbs	13.2 lbs	22.4 lbs
SC06H(G)	21.4 lbs	21.4 lbs	13.2 lbs	22.4 lbs
SC08H(G)	21.4 lbs	21.4 lbs	13.2 lbs	22.4 lbs
SC04Q(G)	21.4 lbs	21.4 lbs	13.2 lbs	22.4 lbs
SC05Q(G)	21.4 lbs	21.4 lbs	13.2 lbs	22.4 lbs
SC06Q(G)	21.4 lbs	21.4 lbs	13.2 lbs	22.4 lbs
SC08Q(G)	21.4 lbs	21.4 lbs	13.2 lbs	22.4 lbs
SC04F(G)	21.4 lbs	21.4 lbs	13.2 lbs	22.4 lbs
SC05F(G)	21.4 lbs	21.4 lbs	13.2 lbs	22.4 lbs
SC06F(G)	21.4 lbs	21.4 lbs	13.2 lbs	22.4 lbs
SC08F(G)	21.4 lbs	21.4 lbs	13.2 lbs	22.4 lbs
SC04L(G)	21.4 lbs	21.4 lbs	13.2 lbs	22.4 lbs
SC06L(G)	21.4 lbs	21.4 lbs	13.2 lbs	22.4 lbs
SC08L(G)	21.4 lbs	21.4 lbs	13.2 lbs	22.4 lbs
SC05W(G)	21.4 lbs	21.4 lbs	13.2 lbs	22.4 lbs

Note: For Surface sterilization solid-bottom containers can be used. 22.4 lbs per shelf, where applicable. A solid-bottom container can be used in the Express, and DUO cycles for surface sterilization only. For the sterilization of lumened devices, SteriTite perforated bottom container suffix G must be used.

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.

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510(k) Summary

K252854

SteriTite Container System with MediTray Products

Date Prepared:	06/02/26
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:	K240898 -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.

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 devices until it is used.

The perforated bottom container configuration is compatible for use with the following steam sterilization cycles:

Steam Cycle with Steam Flush Pressure Pulses (SFPP):
-At 132°C for 4 minutes with a 30-minute dry time
-At 135°C for 3 minutes with a 30-minute dry time

Note: The validation studies were performed using a 4 SFPP pulse cycle with a validation load consisting of unwrapped metal items with a total weight of 25 lbs. (including the SteriTite container).

In addition, the SteriTite container, also available with a solid bottom, is compatible with low-temperature sterilizers, and is compatible with the following sterilizers and cycles identified below:

- SteriTite solid bottom Container: STERRAD 100NX - Express Cycle (surface sterilization of medical devices only; no lumens).

  Note: The validation studies were performed using a validation load consisting of a da Vinci X/Xi 8mm Endoscope with a total weight of 22.4 lbs. (including the SteriTite container).

- SteriTite solid bottom Container: STERRAD 100NX - DUO Cycle (surface sterilization of medical devices only; no lumens).

  Note: The validation studies were performed using a validation load consisting of non-lumened devices with a total weight of 13.2 lbs. (including the SteriTite container).

  Refer to the specific Sterilizer user manual for information regarding the processing of appropriate devices and device types. See labeling for tables of compatible devices and maximum load weight recommendations including the weight of the sterilization container.

The following tables (Table 1 and Table 2) display the SteriTite part numbers and the sterilizers they are compatible with:

Table 1. SteriTite Perforated Bottom Container Compatibility with SFPP and Pre vacuum Steam Sterilizers.

Part Number	Description	SFPP	Gravity Steam
SC02MG	2” High Mini-Size w/ Perforated Base	Yes	Yes
SC03MG	3” High Mini-Size w/ Perforated Base	Yes	Yes
SC04MG	4” High Mini-Size w/ Perforated Base	Yes	Yes
SC02NG	2” High Narrow-Size w/ Perforated Base	Yes	Yes
SC03NG	3” High Narrow-Size w/ Perforated Base	Yes	Yes
SC03NLG	3” High Narrow Long-Size w/ Perforated Base	N/A	Yes
SC04NLG	4” High Narrow Long-Size w/ Perforated Base	N/A	Yes
SC05NLG	5” High Narrow Long -Size w/ Perforated Base	N/A	Yes
SC04HG	4” High Half-Size w/ Perforated Base	Yes	Yes
SC05HG	5” High Half-size w/ Perforated Base	Yes	Yes
SC06HG	6” High Half-Size w/ Perforated Base	Yes	Yes
SC08HG	8” High Half-Size w/ Perforated Base	N/A	Yes
SC04QG	4” High 3/4 Size w/ Perforated Base	Yes	Yes
SC05QG	5” High 3/4 Size w/ Perforated Base	Yes	Yes
SC06QG	6” High 3/4 Size w/ Perforated Base	Yes	Yes
SC08QG	8” High 3/4 Size w/ Perforated Base	N/A	Yes
SC04FG	4” High Full-size w/ Perforated Base	Yes	Yes
SC05FG	5” High Full-size w/ Perforated Base	Yes	Yes
SC06FG	6” High Full-size w/ Perforated Base	Yes	Yes
SC08FG	8” High Full-size w/ Perforated Base	N/A	Yes
SC04LG	4” High Long-size w/ Perforated Base	N/A	Yes
SC06LG	6” High Long-size w/ Perforated Base	N/A	Yes
SC08LG	8” High Long-size w/ Perforated Base	N/A	Yes
SC05WG	5” High Wide Size w/ Perforated Base	N/A	Yes

Note: Perforated bottom containers with part numbers with suffix (G) may be used in any sterilization modality. SteriTite containers with solid bottom may be used in pre-vacuum steam sterilization as well as low temperature modalities.
N/A notes that the specified container does not fit into the sterilizer chamber because of length or width.

Table 2. SteriTite Solid Bottom Container Compatibility with STERRAD 100NX and Steris V-Pro sterilizers

Part Number	Description	STERRAD 100NX	V-Pro s2/60	V-Pro maX/maX2
SC02M	2” High Mini-Size w/ Solid Base	Yes	Yes	Yes
SCO3M	3” High Mini-Size w/ Solid Base	Yes	Yes	Yes
SCO4M	4” High Mini-Size w/ Solid Base	Yes	Yes	Yes
SC02N	2” High Narrow-Size w/ Solid Base	Yes	Yes	Yes
SC03N	3” High Narrow-Size w/ Solid Base	Yes	Yes	Yes
SC03NL	3” High Narrow Long-Size w/ Solid Base	Yes	Yes	Yes
SC04NL	4” High Narrow Long-Size w/ Solid Base	Yes	Yes	Yes
SC05NL	5” High Narrow Long -Size w/ Solid Base	Yes	Yes	Yes
SC04H	4” High Half-Size w/ Solid Base	Yes	Yes	Yes
SC05H	5” High Half-size w/ Solid Base	Yes	Yes	Yes
SC06H	6” High Half-Size w/ Solid Base	Yes	Yes	Yes
SC08H	8” High Half-Size w/ Solid Base	Yes	Yes	Yes
SC04Q	4” High 3/4 Size w/ Solid Base	Yes	Yes	Yes
SC05Q	5” High 3/4 Size w/ Solid Base	Yes	Yes	Yes
SC06Q	6” High 3/4 Size w/ Solid Base	Yes	Yes	Yes
SC08Q	8” High 3/4 Size w/ Solid Base	Yes	Yes	Yes
SC04F	4” High Full-size w/ Solid Base	Yes	Yes	Yes
SC05F	5” High Full-size w/ Solid Base	Yes	Yes	Yes
SC06F	6” High Full-size w/ Solid Base	Yes	Yes	Yes
SC08F	8” High Full-size w/ Solid Base	Yes	Yes	Yes
SC04L	4” High Long-size w/ Solid Base	Yes	N/A	Yes
SC06L	6” High Long-size w/ Solid Base	Yes	N/A	Yes
SC08L	8” High Long-size w/ Solid Base	Yes	N/A	Yes
SC05W	5” High Wide Size w/ Solid Base	Yes	N/A	Yes

Note: Perforated bottom containers with part numbers with suffix (G) may be used in any sterilization modality. SteriTite containers with solid bottom may be used in pre-vacuum steam sterilization as well as low temperature modalities such as EtO, V-Pro, and in STERRAD sterilizers for surface sterilization have no G as a suffix in the part number.
N/A notes that the specified container does not fit into the sterilizer chamber because of length or width.

Table 3. SteriTite Container maximum load weight in Steam Sterilization

Part Number	Pre-vacuum Steam Cycle	Gravity Cycle	SFPP Cycle
SC02M(G)	35lbs	35lbs	25lbs
SC03M(G)	35lbs	35lbs	25lbs
SC04M(G)	35lbs	35lbs	25lbs
SC02N(G)	35lbs	35lbs	25lbs
SC03N(G)	35lbs	35lbs	25lbs
SC03NL(G)	35lbs	35lbs	N/A
SC04NL(G)	35lbs	35lbs	N/A
SC05NL(G)	35lbs	35lbs	N/A
SC04H(G)	35lbs	35lbs	25lbs
SC05H(G)	35lbs	35lbs	25lbs
SC06H(G)	35lbs	35lbs	25lbs
SC08H(G)	35lbs	35lbs	N/A
SC04Q(G)	35lbs	35lbs	25lbs
SC05Q(G)	35lbs	35lbs	25lbs
SC06Q(G)	35lbs	35lbs	25lbs
SC08Q(G)	35lbs	35lbs	N/A
SC04F(G)	35lbs	35lbs	25lbs
SC05F(G)	35lbs	35lbs	25lbs
SC06F(G)	35lbs	35lbs	25lbs
SC08F(G)	35lbs	35lbs	N/A
SC04L(G)	35lbs	35lbs	N/A
SC06L(G)	35lbs	35lbs	N/A
SC08L(G)	35lbs	35lbs	N/A
SC05W(G)	35lbs	35lbs	N/A

N/A notes that the specified container does not fit into the sterilizer chamber because of length or width.

Table 4. SteriTite Container in STERRAD 100NX Maximum Load Weight

Part Number	Total Load Weight in 100NX Standard Cycle	Total Load Weight in 100NX Flexible Cycle	Total Load Weight in 100NX DUO Cycle	Total Load Weight in 100NX Express Cycle
SC02M(G)	21.4 lbs	21.4 lbs	13.2 lbs	22.4 lbs
SC03M(G)	21.4 lbs	21.4 lbs	13.2 lbs	22.4 lbs
SC04M(G)	21.4 lbs	21.4 lbs	13.2 lbs	22.4 lbs
SC02N(G)	21.4 lbs	21.4 lbs	13.2 lbs	22.4 lbs
SC03N(G)	21.4 lbs	21.4 lbs	13.2 lbs	22.4 lbs
SC03NL(G)	21.4 lbs	21.4 lbs	13.2 lbs	22.4 lbs
SC04NL(G)	21.4 lbs	21.4 lbs	13.2 lbs	22.4 lbs
SC05NL(G)	21.4 lbs	21.4 lbs	13.2 lbs	22.4 lbs
SC04H(G)	21.4 lbs	21.4 lbs	13.2 lbs	22.4 lbs
SC05H(G)	21.4 lbs	21.4 lbs	13.2 lbs	22.4 lbs
SC06H(G)	21.4 lbs	21.4 lbs	13.2 lbs	22.4 lbs
SC08H(G)	21.4 lbs	21.4 lbs	13.2 lbs	22.4 lbs
SC04Q(G)	21.4 lbs	21.4 lbs	13.2 lbs	22.4 lbs
SC05Q(G)	21.4 lbs	21.4 lbs	13.2 lbs	22.4 lbs
SC06Q(G)	21.4 lbs	21.4 lbs	13.2 lbs	22.4 lbs
SC08Q(G)	21.4 lbs	21.4 lbs	13.2 lbs	22.4 lbs
SC04F(G)	21.4 lbs	21.4 lbs	13.2 lbs	22.4 lbs
SC05F(G)	21.4 lbs	21.4 lbs	13.2 lbs	22.4 lbs
SC06F(G)	21.4 lbs	21.4 lbs	13.2 lbs	22.4 lbs
SC08F(G)	21.4 lbs	21.4 lbs	13.2 lbs	22.4 lbs
SC04L(G)	21.4 lbs	21.4 lbs	13.2 lbs	22.4 lbs
SC06L(G)	21.4 lbs	21.4 lbs	13.2 lbs	22.4 lbs
SC08L(G)	21.4 lbs	21.4 lbs	13.2 lbs	22.4 lbs
SC05W(G)	21.4 lbs	21.4 lbs	13.2 lbs	22.4 lbs

Note: For Surface sterilization solid-bottom containers can be used. 22.4 lbs per shelf, where applicable. A solid-bottom container can be used in the Express, and DUO cycles for surface sterilization only. For the sterilization of lumened devices, SteriTite perforated bottom container suffix G must be used.

Comparison of Technological Characteristics

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 sterilization cycle claims.

Element	Predicate K240898	Subject Device K252854	Comparison
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. 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 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 devices until it is used. The perforated bottom container configuration is compatible for use with the following steam sterilization cycles: Steam Cycle with Steam Flush Pressure Pulses (SFPP): -At 132°C for 4 minutes with a 30-minute dry time -At 135°C for 3 minutes with a 30-minute dry time Note: The validation studies were performed using a 4 SFPP pulse cycle with a validation load consisting of unwrapped metal items with a total weight of 25 lbs. (including the SteriTite container). In addition, the SteriTite container, also available with a solid bottom, is compatible with low-temperature sterilizers, and is compatible with the following sterilizers and cycles identified below: - SteriTite solid bottom Container: STERRAD 100NX - Express Cycle (surface sterilization of medical devices only; no lumens). Note: The validation studies were performed using a validation load consisting of a da Vinci X/Xi 8mm Endoscope with a total weight of 22.4 lbs. (including the SteriTite container). - SteriTite solid bottom Container: STERRAD 100NX - DUO Cycle (surface sterilization of medical devices only; no lumens). Note: The validation studies were performed using a validation load consisting of non-lumened devices with a total weight of 13.2 lbs. (including the SteriTite container).	Similar; Different sterilization cycle claims for the subject device. Performance testing was done to support these new sterilization cycle claims.

Element	Predicate K240898	Subject Device K252854	Comparison
Materials of construction	Anodized aluminum Stainless steel hardware Silicone gaskets	Same	Same
Device Design	•Off set vent pattern •Disposable filter in lid •Interchangeable filter retention plates •Recessed gasket	Same	Same
Sterilant Penetration for Low Temperature Sterilization	Lumens and Surface sterilization	Surface sterilization only	Different
Maintenance of Sterility	One year	One year	Same
Patient Contact	Indirect	Indirect	Same
Reusable	Yes	Yes	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 ST79.

Performance Testing	Standard	Purpose	Results
Maintenance of Sterility	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

Conclusion

The conclusion drawn from the nonclinical tests demonstrates 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 K240898.