August 6, 2020

Avalign Technologies, Inc.
Heidi Funston
Design Quality Engineering Manager
8727 Clinton Park Dive
Fort Wayne, Indiana 46825

Re: K193066
Trade/Device Name: Steripack cases and Tray Systems
Regulation Number: 21 CFR 880.6850
Regulation Name: Sterilization Wrap
Regulatory Class: Class II
Product Code: KCT
Dated: June 30, 2020
Received: July 7, 2020

Dear Heidi Funston:

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 Ramesh K. Panguluri, Ph.D.
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K193066

Device Name

Steripack Instrument Case and Tray System

Indications for Use *(Describe)*

The Steripack case and tray system are intended for use in healthcare facilities to organize, enclose, sterilize, transport, and store medical devices and other instrumentation between surgical and other medical uses.

The Steripack case and tray system are not intended on their own to maintain sterility; they are intended to be used in conjunction with a legally marketed, validated, FDA-cleared sterilization wrap.

Sterilization validation for the worst-case Steripack cases and tray system included surgical instrument such as rongeur forceps, endoscopes, wrenches, cutters, pliers, etc. The Steripack cases and tray system were validated for up to a 9.35 lb (4.24 kg) load of metal instruments and polymer handled instruments.

Sterilization Parameters:

Cycle Type: Prevacuum
Temperature: 132°C (270°F)
Exposure Time: 4 Minutes
Pulses: 3
Drying Time: 40 Minutes

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

Date Prepared:	August 6, 2020
Company Name:	Avalign Technologies, Inc. 8727 Clinton Park Drive Fort Wayne, IN 46825
Contact Person:	Heidi Funston Design Quality Engineering Manager Avalign Technologies, Inc. Phone: (574) 933-3344 Email: hfunston@avalign.com
510(k) Number:	K193066
Trade name:	Steripack Case and Tray Systems
Classification Name:	Sterilization Wrap Containers, Trays, Cassettes & Other Accessories
Regulation Number:	21 CFR 880-6850
Regulatory Class:	Class II
Device Panel:	General Hospital
Product Code:	KCT

Predicate Device:

Medtronic Transportation/Sterilization Cassettes (Medtronic Sofamor Danek, USA, Inc. (K163279) cleared by FDA on February 23, 2017.

Device Description:

Steripack Case and Tray Systems are utilized to secure medical instruments during transport, storage and processing (cleaning and sterilization). Orthopedic instruments and

implants used in medical procedures are held in preconfigured cases and trays to facilitate transport to and from surgery and during cleaning and sterilization processes.

Some of the Case/Tray Systems in the Steripack line are preconfigured for a specific type instrument or surgical procedure. Other Cases/Trays in the Steripack line have components that are sold separately so the system can be configured based on the use.

Each Steripack Case and Tray Systems consist of multiple components designated to be integrated into a single unit. Which protects the interior components during the transportation, processing, and storage. All the component of the Steripack Case and Tray Systems are perforated with an evenly distributed hole pattern and are designed for stem steam sterilization. Since the Steripack Case and Tray Systems are perforated, an FDA cleared wrap must be used for sterilization purposes and to maintain the sterility of the contents. The Steripack Case and Tray Systems are designed to be used with standard autoclaves used in the hospitals and healthcare facilities.

List of Steripack Item numbers

Item number	**Specification/ dimensions**
2000-100-022	External size: 3.5” x 26” x 3.5” Internal size: 3.5” x 26” x 3.5”
2000-100-023	External size: 6.5” x 31” x 3” Internal size: 6” x 30” x 2.5”
2000-100-017	External size: 11” x 27” x 8” Internal size: 10.7” x 25.62” x 7.66”
2000-100-001	External size: 9” x 10” x 3” Internal size: 8.47” x 8.68” x 2.55”
2000-100-011	External size: 3” x 11” x 2.5” Internal size: 2.93” x 10.93” x 2.5”
2000-100-005	External size: 9” x 20” x 4” Internal size: 8.47” x 18.68” x 3.55”
2000-100-006	External size: 4” x 17.5” x 1.5” Internal size: 3.57” x 17.19” x 1.35”
2000-100-021	External size: 9” x 9” x 1.5” Internal size: 8.57” x 8.72” x 1.18”
2000-100-019	External size: 3” x 18” x 2.5” Internal size: 2.93” x 17.93” x 2.46”
2000-100-004	External size: 9” x 20” x 4” Internal size: 8.47” x 18.68” x 3.55”
2000-100-015	External size: 11” x 23” x 8” Internal size: 10.70” x 21.62” x 7.66”
2000-100-003	External size: 5” x 10.5” x 2” Internal size: 4.50” x 10.29” x 1.63”
2000-100-020	External size: 11” x 23” x 3.5” Internal size: 10.70” x 21.62” x 3.41”

Item number	Specification/ dimensions
2000-100-030	External size: 11” x 23” x 5” Internal size: 10.70” x 21.62” x 4.91”
2000-100-031	External size: 11” x 23” x 5” Internal size: 10.7” x 21.62” x 4.91”
2000-100-032	External size: 11” x 23” x 5” Internal size: 10.70” x 21.62” x 4.91”
2000-100-029	Tray size: 10.5” x 21.5” x 2”
2000-100-034	External size: 11” x 27” x 3.5” Internal size: 10.88” x 25.62” x 3.41”
2000-100-035	External size: 10” x 21.5” x 2.5” Internal size: 9.72” x 20.65” x 2.42”
2000-100-026	External size: 9.5” x 20” x 5.5” Fits in 10” x 20” x 6” container
2000-100-018	External size: 9.5 “ x 20” x 5.5” Fits in 10” x 20” x 6” container
2000-100-079	External size: 9.9” x 19.5” x 4.9” fits in a 10” x 20” x 6” container
2000-100-027	External size: 9” x 11.5” x 3” Internal size: 8.57” x 11.12” x 2.38”
2000-100-010	External size: 9” x 13” x 6” Internal size: 8.59” x 12.09” x 5.84”
2000-100-025	External size: 9” x 15” x 5” Internal size: 8.59” x 13.84” x 4.84”
2000-204-022	Tray size: 10.5” x 21.5” x 2.25”
2000-100-121	External size: 5” x 10.5” x 2” Internal size: 4.50” x 10.29” x 1.53”
2000-100-122	External size: 10.5” x 10.5” x 2.5” Internal size: 9.84” x 10.2” x 2.32”
2000-100-123	External size: 10.5” x 10.5” x 1.5” Internal size: 9.84” x 10.2” x 1.23”
2000-100-124	External size: 10.5” x 15” x 1.5” Internal size: 9.84” x 14.68” x 1.23”
2000-100-125	External size: 10.5” x 15” x 2.5” Internal size: 9.84” x 14.60” x 2.32”
2000-100-126	External size: 10” x 19.5” x 2.5” Internal size: 9.84” x 19” x 2.32”

Item number	Specification/ dimensions
2000-100-127	External size: 10.5” x 15” x 2.5” Internal size: 9.84” x 14.6” x 2.32”
2000-100-128	External size: 10.5” x 19.5” x 2.5” Internal size: 9.84” x 19” x 2.32”
2000-100-037	19.50” x 9.90” x 4.90”
2000-100-129	10.73” x 15.48” x 2.64”
2000-100-131	10.60” x 10.55” x 1.55”
2000-100-104	9" x 13.34" x 7.13"
2000-100-132	External size: 10.50” x 15” x 1.50” Internal size: 9.84” x 14.68” x 1.23”
2000-100-133	External size: 19.88” x 10.74” x 2.63”
2000-100-115	Lap Chole Case, w/latches, one level,without Insert, 11" x 23" x 8"
2000-100-116	Lap Chole Case 11" x 27" x 8"without insert
3088-100-001	Terumo Cardiovascular Systems Component Sterilization Tray
3089-100-001	Terumo Cardiovascular Systems Endoscope Sterilization Tray
3317-100-002	Surgical Case
2000-100-036	Accessory Box single level, 1.5" x 3.5" x 1"
2000-100-130	Accessory Box single level, with hardware (2 screws & nuts), with pin mat,1.5" x 3.5" x 1"
2000-100-134	Accessory Box single level, Scanlon only with hardware (2 screws & nuts), with embossed pin mat, 1.5"x3.5"x1"
2000-100-117	Accessory Box single level, with hardware (2 screws & nuts) 1.5" x 3.5" x 1"
2000-100-135	Accessory Box single level, Scanlon only with hardware (2 screws & nuts), with embossed pin mat, 1.5"x3.5"x1"
2000-100-119	Accessory Box single level, 1.5" x 3.5" x 1"

Item number	Specification/ dimensions
2000-100-016	External size: 1.5” x 3.5” x 1” Internal size: 1.44” x 3.16” x 1”
2000-100-036	External size: 1.5” x 3.5” x 1” Internal size: 1.44” x 3.16” x 1”
2000-162-071	Universal keyhole bracket, 10 - 5 - 3 mm diameters in one vertical slot 5” long, 6 position
2000-162-054	Universal keyhole bracket, 10 - 5 - 3 mm diameters in one vertical slot 7.5” long, 6 position
2000-162-056	Universal keyhole bracket, 10 - 5 - 3 mm diameters in one vertical slot 7.5” long, 10 position
2000-162-052	Universal keyhole bracket, 10 - 5 - 3 mm diameters in one vertical slot 9.25” long, 14 position
2000-162-055	Universal keyhole bracket, 10 - 5 - 3 mm diameters in one vertical slot 10” long , 15 position
2000-162-044	Slotted U Brackets (2mm) 1.0”
2000-162-045	Slotted U Brackets (3mm)1.0”
2000-162-046	Slotted U Brackets (4mm) 1.0”
2000-162-047	Slotted U Brackets (5mm)1.0”
2000-162-048	Slotted U Brackets (6mm)1.0”
2000-162-049	Slotted U Brackets (7mm)1.0”
2000-162-050	Slotted U Brackets (10mm)1.0”
2000-162-051	Slotted U Brackets (12mm) 1.0”
2000-162-036	Slotted U Brackets (2mm)1.5”
2000-162-037	Slotted U Brackets (3mm)1.5”
2000-162-038	Slotted U Brackets (4mm) 1.5”
2000-162-039	Slotted U Brackets (5mm) 1.5”
2000-162-040	Slotted U Brackets (6mm) 1.5”

Item number	Specification/ dimensions
2000-162-041	Slotted U Brackets (7mm) 1.5”
2000-162-042	Slotted U Brackets (10mm) 1.5”
2000-162-043	Slotted U Brackets (12mm) 1.5”
2000-162-030	Pass Thru Brackets (6mm) 1.0”
2000-162-031	Pass Thru Brackets (7mm) 1.0”
2000-162-032	Pass Thru Brackets (9mm) 1.0”
2000-162-033	Pass Thru Brackets (10mm) 1.0”
2000-162-034	Pass Thru Brackets (12mm) 1.0”
2000-162-035	Pass Thru Brackets (13mm) 1.0”
2000-162-024	Pass Thru Brackets (6mm) 1.5”
2000-162-025	Pass Thru Brackets (7mm) 1.5”
2000-162-026	Pass Thru Brackets (9mm) 1.5”
2000-162-027	Pass Thru Brackets (10mm) 1.5”
2000-162-028	Pass Thru Brackets (12mm) 1.5”
2000-162-029	Pass Thru Brackets (13mm) 1.5”
2000-162-014	Keyhole Brackets (2mm) 1.0”
2000-162-015	Keyhole Brackets (3 mm) 1.0”
2000-162-016	Keyhole Brackets (4mm) 1.0”
2000-162-017	Keyhole Brackets (5 mm) 1.0”
2000-162-019	Keyhole Brackets (6 mm) 1.0”
2000-162-018	Keyhole Brackets (7 mm) 1.0”
2000-162-020	Keyhole Brackets (10 mm) 1.0”

Item number	Specification/ dimensions
2000-162-021	Keyhole Brackets (12 mm) 1.0”
2000-162-022	Keyhole Brackets (13 mm) 1.0”
2000-162-001	Keyhole Brackets (2 mm) 1.5”
2000-162-002	Keyhole Brackets (3 mm) 1.5”
2000-162-003	Keyhole Brackets (4 mm) 1.5”
2000-162-004	Keyhole Brackets (5 mm) 1.5”
2000-162-005	Keyhole Brackets (6 mm) 1.5”
2000-162-006	Keyhole Brackets (7 mm) 1.5”
2000-162-007	Keyhole Brackets (10 mm) 1.5”
2000-162-008	Keyhole Brackets (12 mm) 1.5”
2000-162-009	Keyhole Brackets (13 mm) 1.5”
2000-162-010	Keyhole Brackets (15mm) 1.5”
2000-162-011	Keyhole Brackets (19 mm) 1.5”
2000-162-012	Keyhole Brackets (22 mm) 1.5”
2000-162-013	Keyhole Brackets (25 mm) 1.5”
2000-162-023	Keyhole Brackets (3-tier 10/5/3mm) 1.5”
2000-162-062	V-Sillicone Retainers 3.38”
2000-162-063	V-Silicone Retainers 4.25”
2000-162-064	V-Silicone Retainers 8.25”
2000-162-065	V-Silicone Retainers 9.50”
2000-162-066	V-Silicone Retainers 14.25”
2000-162-067	V-Silicone Retainers 18.25”

Item number	Specification/ dimensions
2000-162-058	“L” brackets to support trays
2000-260-002	SS Riser Bracket, .5” x 1.5”, used to elevate single wide brackets from the case floor
2000-300-058	Pin Mate Grid Style 4.50” Length, 1.00” Width
2000-300-059	Pin Mate Grid Style 9.63” Length, 1.00” Width
2000-300-060	Pin Mate Grid Style 14.25” Length, 1.00” Width
2000-300-061	Pin Mate Grid Style 18.25” Length, 1.00” Width
2000-300-062	Pin Mate Grid Style 4.50” Length, 1.50” Width
2000-300-063	Pin Mate Grid Style 7.13” Length, 1.50” Width
2000-300-064	Pin Mate Grid Style 9.12” Length, 1.50” Width
2000-300-065	Pin Mate Grid Style 16.88” Length, 3.45” Width
2000-300-066	Pin Mate Grid Style 10.12” Length, 4.25” Width
2000-300-067	Pin Mate Grid Style 9.75” Length, 4.25” Width
2000-300-068	Pin Mate Grid Style 8.56” Length, 8.12” Width
2000-300-069	Pin Mate Grid Style 18.25” Length, 8.25” Width
2000-300-070	Pin Mate Grid Style 14.13” Length, 9.63” Width
2000-300-071	Pin Mate Grid Style 18.25” Length, 9.63” Width
2000-300-072	Pin Mate Grid Style 9.50” Length, 9.50” Width
2000-300-073	Pin Mate Grid Style 18.25” Length, 10.12” Width
2000-300-074	Pin Mate Grid Style 18.25” Length, 1.50” Width
2000-300-075	Pin Mate Grid Style 6.75” Length, 10.12” Width
2000-300-076	Pin Mate Grid Style 3.40” Length, 10.12” Width

Item number	Specification/ dimensions
2000-300-077	Pin Mate Grid Style 6.50” Length, 10.12” Width
2000-300-078	Pin Mate Grid Style 5.00” Length, 10.12” Width
2000-300-079	Pin Mate Grid Style 5.75” Length, 10.12” Width
2000-300-080	Pin Mate Grid Style 17.50” Length, 6.75” Width
2000-300-081	Pin Mate Grid Style 10.12” Length, 6.00” Width
2000-300-082	Pin Mate Grid Style 10.12” Length, 6.00” Width
2000-300-083	Pin Mate Grid Style 7.63” Length, 4.00” Width
2000-300-084	Pin Mate Grid Style 15.25” Length, 6.00” Width
2000-300-085	Pin Mate Grid Style 14.13” Length, 9.63” Width
2000-300-086	Pin Mate Grid Style 9.50” Length, 9.50” Width
2000-300-087	Pin Mate Grid Style 4.50” Length, 1.50” Width
2000-300-088	Pin Mate Grid Style 10.12” Length, 6.00” Width
2000-300-089	Pin Mate Grid Style 18.25” Length, 9.63” Width
2000-300-090	Pin Mate Grid Style 3.15” Length, 1.42” Width
2000-300-091	Pin Mate Grid Style 9.00” Length, 7.00” Width
2000-300-092	Pin Mate Grid Style 10.00” Length, 9.00” Width
2000-300-093	Pin Mate Grid Style 7.00” Length, 10.50” Width
2000-300-094	Pin Mate Grid Style 7.50” Length, 13.50” Width

Indication for Use:

The Steripack case and tray system are intended for use in healthcare facilities to organize, enclose, sterilize, transport, and store medical devices and other instrumentation between surgical and other medical uses.
The Steripack case and tray system are not intended on their own to maintain sterility; they are intended to be used in conjunction with a legally marketed, validated, FDA- cleared sterilization wrap.
Sterilization validation for the worst-case Steripack Case and Tray Systems included surgical instrument such as rongeur forceps, wrenches, cutters, pliers, etc. The Steripack Case and Tray Systems were validated, for up to a 9.35 lb (4.24 kg) load of metal instruments and polymer handled instruments.

Sterilization Parameters:

Cycle Type:	Prevacuum
Temperature:	132 °C (270°F)
Exposure Time:	4 Minutes
Pulses:	3
Drying Time:	40 Minutes

Technological Characteristics
Table 5.1 displays the comparison of the Steripack Case and Tray Systems compared against the predicate.

Table 5.1- Comparison of Steripack Case and Tray Systems (K193066) and Medtronic Transportation/Sterilization Cassettes (K163279)

Feature	Steripack Case and Tray Systems (K193066)	Medtronic Transportation/Sterilization Cassettes (K163279)	Comparison
Trade Name	Steripack Case and Tray Systems	Medtronic Transportation/Sterilization Cassettes	N/A
Fundamental Scientific Technology	Sterilization Cassette	Sterilization Cassette	Same
Intended Use	The Steripack case and tray system are intended for use in healthcare facilities to organize, enclose, sterilize, transport, and store medical devices and other instrumentation between surgical and other medical uses. The Steripack case and tray system are not intended on their own to maintain sterility; they are intended to be used in conjunction with a legally marketed, validated, FDA-cleared sterilization wrap.	The Medtronic Transportation/Sterilization Cassettes are intended for use in healthcare facilities to organize, enclose, sterilize, transport, and store medical devices and other instrumentation between surgical and other medical uses. The Medtronic Transportation/Sterilization Cassettes are not intended on their own to maintain sterility; it is intended to be used in conjunction with a legally marketed, validated, FDA-cleared sterilization wrap.	Same
Product Code	KCT	KCT	Same
Material Composition	Thermoplastic polymers, aluminum, Silicone and stainless steel	Thermoplastic polymers, aluminum, and stainless steel	Similar

Feature	Steripack Case and Tray Systems (K193066)	Medtronic Transportation/Sterilization Cassettes (K163279)	Comparison
Design	A base, a lid with a locking latch, and individual inserts	A base, a lid with a locking latch, and individual inserts	Same
Dimensions	The greatest challenge dimension was assessed to be: 21.06 x 10.00 x 4.28 inches The inserts are offered in different sizes	The greatest challenge dimension was assessed to be: 22.75 x 11.26 x 5.51 inches The inserts are offered in different sizes	Similar
Configuration	Perforated bases, lids, and inserts	Perforated bases, lids, and inserts	Same
Volume to Vent Ratio	All Vent to Volume Ratios:	Unable to access the challenge volume to vent ratio data. The challenge device was the subject of the sterilization validation.	Similar

Item Number	VtoV Ratio
2000-100-022	4.290
2000-100-023	4.902
2000-100-017	6.584
2000-100-001	7.240
2000-100-011	0.811
2000-100-005	7.383
2000-100-006	4.950
2000-100-021	3.871
2000-100-019	3.093
2000-100-004	7.383
2000-100-015	6.609
2000-100-003	6.039
2000-100-020	8.177
2000-100-030	10.476
2000-100-031	10.476
2000-100-032	10.476
2000-100-029	10.409
2000-100-034	7.956
2000-100-035	6.466
2000-100-026	6.068
2000-100-018	9.302
2000-100-079	Open Case
2000-100-027	6.360
2000-100-010	5.053
2000-100-025	4.419
2000-204-022	Open Case
2000-100-121	6.039
2000-100-122	5.061
2000-100-123	3.037
2000-100-124	2.945
2000-100-125	4.674

	2000-100-126	4.651		
	2000-100-127	4.674		
	2000-100-128	4.758		
	2000-100-037	N/A - Accessory		
	2000-100-129	4.674		
	2000-100-131	2.945		
	2000-100-104	5.053		
	2000-100-132	2.945		
	2000-100-133	7.201		
	2000-100-115	Open Case		
	2000-100-116	Open Case		
	3088-100-001	2.420		
	3089-100-001	0.701		
	3317-100-002	2.441		
Percent Perforation	Evenly distributed hole pattern.		Evenly distributed hole pattern.	Same
Sterilization Method	Pre-Vacuum		Pre-Vacuum and Gravity Displacement	Similar

<table>
<tr><th>Feature</th><th>Steripack Case and Tray Systems (K193066)</th><th colspan="4">Medtronic Transportation/Sterilization Cassettes (K163279)</th><th>Comparison</th></tr>
<tr><td>Sterilization Parameters</td><td>Cycle Type: Prevacuum
Temperature: 132 °C (270°F)
Exposure Time: 4 Minutes
Pulses: 3
Drying Time: 40 Minutes</td><td>Cycle</td><td>Temperature</td><td>Exposure Time</td><td>Minimum Dry Time</td><td>Similar</td></tr>
<tr><td></td><td></td><td>Gravity Displacement</td><td>270°F (132°C)</td><td>30 Minutes</td><td>30 Minutes</td><td></td></tr>
<tr><td></td><td></td><td>Gravity Displacement</td><td>275°F (135°C)</td><td>15 Minutes</td><td>30 Minutes</td><td></td></tr>
<tr><td></td><td></td><td>Gravity Displacement</td><td>250°F (121°C)</td><td>10 Minutes</td><td>30 Minutes</td><td></td></tr>
<tr><td></td><td></td><td>Dynamic Air Removal (4 Pulses)</td><td>270°F (132°C)</td><td>4 Minutes</td><td>30 Minutes</td><td></td></tr>
<tr><td></td><td></td><td>Dynamic Air Removal (4 Pulses)</td><td>275°F (135°C)</td><td>3 Minutes</td><td>30 Minutes</td><td></td></tr>
<tr><td>Reusable</td><td>Yes</td><td colspan="4">Yes</td><td>Same</td></tr>
</table>

Summary of Nonclinical Testing:

Shown below is the summary table of the nonclinical testing that was performed with the subject device to demonstrate that it met the acceptance criteria in the standard.

Name of the Methodology and Citation Name	Purpose	Acceptance Criteria	Results
Handle Durability Test ANSI/AAMI ST77:2006(R)2010	This test was performed to determine the ability of the case handle to maintain the lid to base connection when subjected to typical forces experienced during routine use. The test was conducted on the three handle styles available in the Steripack case and tray system: U type, rail style, and ring style	50 lb load to be held for 30 minutes (safety factor of 2X max load of 25 lbs) Source: ANSI/AAMI ST77:2006(R)2010 indicates maximum load for reusable case and trays are 25 lbs.	The three handle styles were able to support the 50 lb load for the required 30 minutes without failure. Therefore, the handle designs meet the requirements of ANSI/AAMI ST77:2006(R)2010 and the handles are safe and effective for use with the Steripack case and tray systems.
Transport / Shipping Test ASTM D4169-09	This test was performed to determine the ability of the Steripack Case and Tray Systems to withstand the shipping and storage requirements during product shipping and transportation. The tests conducted per ASTM D4169-09 were Manual Handling, Vehicle Stacking, Loose-load Vibration, Low Pressure Hazard, Vehicle Vibration, and Concentrated Impact.	The case system will be considered to be acceptable if it meets the following acceptance criteria: • Instruments must remain in their designated location inside the outer case and lid system. • There must be no damage to the case/tray that would prevent it from holding and protecting the instruments for transport or sterilization processing. • There must be no damage to the internal instruments. Source: ASTM D4169-09	**Test** / **Results** Manual Handling: Acceptance criteria were met, instruments were held, no damage was inflicted on the case and tray system or the enclosed instruments. Vehicle Stacking: Acceptance criteria were met, instruments were held, no damage was inflicted on the case and tray system or the enclosed instruments. Loose-load Vibration: Acceptance criteria were met, instruments were held, no damage was

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			inflicted on the case and tray system or the enclosed instruments.
			Low Pressure Hazard: Acceptance criteria were met, instruments were held, no damage was inflicted on the case and tray system or the enclosed instruments.
			Vehicle Vibration: Acceptance criteria were met, instruments were held, no damage was inflicted on the case and tray system or the enclosed instruments.
			Concentrated Impact: Acceptance criteria were met, instruments were held, no damage was inflicted on the case and tray system or the enclosed instruments.
Life Cycle Testing / Repeated Reprocessing ANSI/AAMI ST77:2006(R)2010.	This test was performed to demonstrate that the Steripack Case and Tray system could withstand repeated reprocessing through a steam sterilization cycle.	After the 100 sterilization cycles the case and tray materials of construction must be durable and compatible with the sterilization process. • No materials may break down. • All handles, latches, and hinges must move freely and as intended. • No visible rust or discoloration is acceptable on laser etching. • Screen print cannot bleed, peel, or shift. • No visible discoloration is acceptable on	After 100 cycles were complete, all functional testing and material requirements described above passed. The only observation made was four of the nylon coated brackets had the nylon coating begin to bubble. This was not deemed a functional failure because the nylon coating did not crack and no metal was exposed.

Name of the Methodology and Citation Name	Purpose	Acceptance Criteria	Results
		stainless steel or anodized components. • Cracking nylon coating or exposed metal through nylon is not acceptable. • Radel and polypropylene cannot be deformed. Source: Test was conducted to show materials meet the durability and sterilization compatibility requirements of ANSI/AAMI ST77:2006(R)2010.	
Sterilant penetration AANSI/AAMI/ISO 17665-1:2006/(R)2013	To validate the sterilization efficacy of the Steripack case and tray worst case volume to vent ratio device, when processed fully loaded in a steam pre-vacuum sterilization cycle at 132° C (270°F) with four (4) minutes of exposure time.	The overkill method was selected to verify the sterilization efficacy of the samples, per AAMI/ISO guidelines. In this method, validation was accomplished by demonstrating that a minimum of 1.0 x 106 highly resistant Geobacillus stearothermophilus spores were killed in a half-cycle (6-log reduction). A full cycle would therefore result in a 12-log reduction of spores and produce a 10-6SAL, which reflects a one-in-a-million chance of a non-sterile item. Source: AANSI/AAMI/ISO 17665-1:2006/(R)2013	Results from testing validate that the Steripack Instrument Tray and Case Systems allow sterilant penetration sufficient to achieve a 10-6 SAL after processing in the pre-vacuum sterilization cycle at 132°C (270°F) and four (4) minutes of exposure time.
Biocompatibility – Thermoplastic Coating (Nylon 11) ANSI/AAMI/ISO 10993-5:2009	Testing performed on the Thermoplastic Coating as manufactured to ensure it meets the Cytotoxicity (MEM elution test) requirements of ISO 10993 for a device with potential indirect patient contact.	Grade ≤ 2 Source: ANSI/AAMI/ISO 10993-5:2009	Test specimen was subjected to a cytotoxicity test ISO MEM elution L-929 cells (ATCC CCL-1). Method: Incubated at 37±1° C with 5±1% CO2 for 72 ± 3 hours. The test article scored a Grade 0, eliciting no cytotoxic effect.
Biocompatibility –	Testing performed	No animals could exhibit	Test specimen was subjected to an

Name of the Methodology and Citation Name	Purpose	Acceptance Criteria	Results
Thermoplastic Coating (Nylon 11) ANSI/AAMI/ISO 10993-1:2009	on the Thermoplastic Coating to ensure it meets the Acute Systemic Toxicity requirements of ISO 10993 for a device with potential indirect patient contact.	clinical signs of toxicity during the 72 hour study period. Source: ANSI/AAMI/ISO 10993-1:2009	Acute Systemic Toxicity test on mice. Method: The extraction mixtures and corresponding control blanks were incubated for 72 ± 2 hours at 50 ± 2 ° C None of the animals on study were observed with abnormal clinical signs indicative of toxicity during the 72 hour test period. All were alive at the end of the 72 hour test duration and body weight loss was within acceptable parameters over the course of the study
Biocompatibility – Thermoplastic Coating (Nylon 11) ANSI/AAMI/ISO 10993-1:2009	Testing performed on the Thermoplastic Coating to ensure it meets the Intracutaneous Irritation requirements of ISO 10993 for a device with potential indirect patient contact.	Extract from the test specimen must not cause local irritation to the dermal tissue of a rabbit. Source: ANSI/AAMI/ISO 10993-1:2009	Test specimen was subjected to an Acute Systemic Toxicity test on mice. Method: The extraction mixtures and corresponding control blanks were incubated for 72 ± 2 hours at 50 ± 2 ° C No significant dermal reactions were observed in the test subjects.
Biocompatibility – Thermoplastic Coating (Nylon 11) ANSI/AAMI/ISO 10993-1:2009	Testing performed on the Thermoplastic Coating to ensure it meets the Implantation Test requirements of ISO 10993 for a device with potential indirect patient contact.	The differences between average scores of the encapsulation of the test article implantation site and the negative control site cannot score greater than 1.0. Source: ANSI/AAMI/ISO 10993-1:2009	Test specimen was subjected to an intramuscular implantation test on rabbits. The test article was implanted in the animal subject for 1 week. Method: test article was cut into pieces approximately 3 mm x 1 0 mm. and instead to the paravertebral muscle. There was no difference (Score of 0) between the average encapsulation scores between the implantation sites and the negative control sites.
Biocompatibility – Thermoplastic Coating (Nylon 11) ANSI/AAMI/ISO 10993-5:2009	Testing performed on the Thermoplastic Coating after sterilization to ensure it meets the Cytotoxicity (MEM elution test) requirements of ISO 10993 for a device with potential indirect patient contact through leachables.	Grade ≤ 2 Source: ANSI/AAMI/ISO 10993-5:2009	The test article induced no cytotoxicity (Grade 0). Therefore the test article is not considered to elicit a cytotoxic effect under the conditions employed.
Biocompatibility – Silicone (Elastomer)	Testing performed on the Silicone Elastomer material	No cytopathic effect. Source:	Cytotoxicity testing reports were provided by the supplier (DOW CORNING). Per biocompatibility

<table>
<tr><th>Name of the Methodology and Citation Name</th><th>Purpose</th><th>Acceptance Criteria</th><th>Results</th></tr>
<tr><td>ANSI/AAMI/ISO 10993-5:2009</td><td>to ensure it meets the Cytotoxicity requirements of ISO 10993 for a device with potential indirect patient contact.</td><td>ANSI/AAMI/ISO 10993-5:2009</td><td>reports, “Cell Culture” test was performed on “Elastomers” and “Cell culture medium extract of elastomer” for the cytotoxicity evaluation.

No Cytopathic effect (morphology changes). No Cytopathic effect (morphology changes): ≥ 75% visibility (by neutral red)</td></tr>
<tr><td>Biocompatibility – Silicone (Elastomer)

ANSI/AAMI/ISO 10993-10:2009</td><td>Testing performed on the Silicone Elastomer material to ensure it meets the Sensitization requirements of ISO 10993 for a device with potential indirect patient contact.</td><td>No sensitization when exposed to an extract of the test article.

Source: ANSI/AAMI/ISO 10993-10:2009</td><td>Skin Sensitization test was performed on Elastomer, Saline Extract of elastomer and Ethanol or acetone extract of elastomer for the sensitization evaluation.

Test meets ISO 10993-1 requirements with no sensitization.</td></tr>
<tr><td>Biocompatibility – Silicone (Elastomer)

ANSI/AAMI/ISO 10993-10:2009</td><td>Testing performed on the Silicone Elastomer material to ensure it meets the Intracutaneous Reactivity requirements of ISO 10993 for a device with potential indirect patient contact.</td><td>Test article to be non-irritating and non-toxic.

Source: ANSI/AAMI/ISO 10993-10:2009</td><td>Intracutaneous reactivity test was performed on Saline Extract of elastomer, Extract if elastomer in 5% ethanol 95% saline, PEG 400 extract of elastomers and Cottonseed oil extract of elastomer for the intracutaneous reactivity evaluation.

The test article was non-irritating and non-toxic relative to controls</td></tr>
<tr><td>Biocompatibility – Silicone (Elastomer)

ANSI/AAMI/ISO 10993-10:2009</td><td>Testing performed on the Silicone Elastomer material to ensure it meets the Systemic Toxicity requirements of ISO 10993 for a device with potential indirect patient contact.</td><td>Test article to be non-irritating and non-toxic.

Source: ANSI/AAMI/ISO 10993-10:2009</td><td>Systemic toxicity test was performed on Saline Extract of elastomer, Extract if elastomer in 5% ethanol 95% saline, PEG 400 extract of elastomers and Cottonseed oil extract of elastomer for the intracutaneous reactivity evaluation.

The test article was non-irritating and non-toxic relative to controls</td></tr>
<tr><td>Biocompatibility – Silicone Elastomer

ANSI/AAMI/ISO 10993-5:2009</td><td>Testing performed on the eight color variations of the Silicone elastomer after sterilization to ensure it meets the Cytotoxicity (MEM elution test) requirements of ISO 10993 for a device with potential indirect patient contact through leachables.</td><td>Grade ≤ 2

Source: ANSI/AAMI/ISO 10993-5:2009</td><td>
<table>
<tr><th>Description</th><th>Test Sample Grade</th></tr>
<tr><td>Test Coupon: Black Silicone Extrusion</td><td>0</td></tr>
<tr><td>Test Coupon: Blue Silicone Extrusion</td><td>1</td></tr>
<tr><td>Test Coupon: Blue V-Rubber Extrusion</td><td>1</td></tr>
<tr><td>Test Coupon: Black Pin Mat</td><td>0</td></tr>
<tr><td>Test Coupon: Blue Pin Mat</td><td>2</td></tr>
<tr><td>Test Coupon: Flat</td><td>0</td></tr>
</table>
</td></tr>
</table>

Name of the Methodology and Citation Name	Purpose	Acceptance Criteria	Results
			<table><tr><td>Bottom Black Pin Mat</td><td></td></tr><tr><td>Test Coupon: Flat Bottom Blue Pin Mat</td><td>0</td></tr><tr><td>Test Coupon: Grid Pin Mat</td><td>0</td></tr></table> All samples met the requirement for a Grade ≤ 2.
Biocompatibility – Anodized Aluminum ANSI/AAMI/ISO 10993-5:2009	Testing performed on the Anodized Aluminum material to ensure it meets the Cytotoxicity requirements of ISO 10993 for a device with potential indirect patient contact.	Grade ≤ 2 Source: ANSI/AAMI/ISO 10993-5:2009	Test article was subjected to a cytotoxicity test ISO MEM elution L-929 cells (ATCC CCL-1). Method: Incubated at 37±1° C with 5±1% CO2 for 48 ± 3 hours The test article scored "0" at 48 ± 3 hours for all 3 cell monolayers.
Biocompatibility – Anodized Aluminum AANSI/AAMI ST 72:2011	Testing performed on the Anodized Aluminum material to ensure it meets the requirements of ANSI/AAMI ST 72 for pyrogenicity.	For a medical device, endotoxin limit is >20 EU/device. Source: AANSI/AAMI ST 72:2011	Test specimen was subjected to a BET test. Method: The extraction was performed by immersing the test article in endotoxin free water and placing it on an orbital shaker in an incubator for 40-60 minutes at 37 - 40°C. The range for the three specimens was <0.972 - <1.28 EU / device. The devices met the acceptance criteria.
Biocompatibility – Stainless Steel ANSI/AAMI/ISO 10993-5:2009	Testing performed on the Stainless Steel material to ensure it meets the Cytotoxicity requirements of ISO 10993 for a device with potential indirect patient contact.	Grade ≤ 2 Source: ANSI/AAMI/ISO 10993-5:2009	The test article was subjected to a cytotoxicity test ISO MEM elution L-929 cells (ATCC CCL-1). Method: Incubated at 37±1° C with 5±1% CO2 for 48 ± 3 hours The test article scored "0" at 48 ± 3 hours for all 3 cell monolayers.
Biocompatibility – Stainless Steel ANSI/AAMI ST 72:2011	Testing performed on the Anodized Aluminum material to ensure it meets the requirements of ANSI/AAMI ST 72 for pyrogenicity.	For a medical device, endotoxin limit is >20 EU/device. Source: ANSI/AAMI ST 72:2011	Test specimen was subjected to a BET test. Method: The extraction was performed by immersing the test article in endotoxin free water and placing it on an orbital shaker in an incubator for 40-60 minutes at 37 - 40°C. The range for the three specimens was <2.93 - <3.02 EU / device. The devices met the acceptance criteria.

Conclusion

The conclusions drawn from the nonclinical tests demonstrate that the subject Steripack Case and Tray Systems devices are as safe, as effective, and perform as well as or better than the legally marketed predicate device Medtronic Transportation/Sterilization Cassettes cleared under K163279.