Wipak OY
% Amanda Singleton
Consultant
Compliance Systems International LLC
39 Lockhart Circle
Amherst, New York 14228

June 27, 2024

Re: K231996
Trade/Device Name: Steriking® LT-Blueline Pouches with Tyvek®
Regulation Number: 21 CFR 880.6850
Regulation Name: Sterilization wrap
Regulatory Class: Class II
Product Code: FRG

Dear Amanda Singleton:

The Food and Drug Administration (FDA) is sending this letter to notify you of an administrative change related to your previous substantial equivalence (SE) determination letter dated September 7, 2023. Specifically, FDA is updating this SE Letter due to the incorrectly attached 510(k) Summary as an administrative correction.

Please note that the 510(k) submission was not re-reviewed. For questions regarding this letter please contact Colin O'Neill, M.B.E., OHT6: Office of Orthopedic Devices, 301-796-6428, Colin.Oneill@fda.hhs.gov.

Sincerely,

Eileen Cadel -S

Digitally signed by Eileen Cadel -S
Date: 2024.06.27 08:54:56 -04'00'

for

Colin O'Neill, M.B.E.
Assistant Director
DHT6B: Division of Spinal Devices
OHT6: Office of Orthopedic Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Wipak OY
% Amanda Singleton
Consultant
Compliance Systems International LLC
39 Lockhart Circle
Amherst, New York 14228

September 7, 2023

Re: K231996
Trade/Device Name: Steriking® LT-Blueline Pouches with Tyvek®
Regulation Number: 21 CFR 880.6850
Regulation Name: Sterilization Wrap
Regulatory Class: Class II
Product Code: FRG
Dated: August 11, 2023
Received: August 11, 2023

Dear Amanda Singleton:

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,

Eileen Cadel -S

Digitally signed by Eileen Cadel -S
Date: 2023.09.07 13:46:02 -04'00'

for

Colin O'Neill, M.B.E.
Assistant Director
DHT6B: Division of Spinal Devices
OHT6: Office of Orthopedic 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)*
K231996

Device Name
Steriking® LT-Blueline Pouches with Tyvek®

Indications for Use *(Describe)*
Steriking® LT-Blueline Pouches with Tyvek® are intended to provide health care workers with an effective method to enclose devices intended for sterilization in the STERIS® V-Pro® Sterilizer Systems.

The device is intended to allow sterilization of enclosed devices and to maintain sterility of the enclosed devices until used up to 1 year post sterilization. The products are for single use only.

Steriking® LT-Blueline Pouches with Tyvek are intended for use in the following STERIS® V-Pro® Sterilization Cycles:
Lumen Cycle
Non Lumen Cycle
Flexible Cycle

Device lumen dimensions:

Flexible Cycle: 1 lumen max and 1 mm min ID x 1050 mm max length for all pouch sizes.

Lumen Cycle: 1 lumen max for all pouch sizes.
1 mm min ID for pouch sizes: 130 x 380 mm, 130 x 270 mm, 90 x 250 mm, 90 x 200 mm
2 mm min ID for pouch sizes: 300 x 450 mm, 250 x 400 mm, 190 x 330 mm
125 mm max length for pouch sizes: 130 x 380 mm, 130 x 270 mm, 90 x 250 mm, 90 x 200 mm
250 mm max length for pouch sizes: 300 x 450 mm, 250 x 400 mm, 190 x 330 mm

Max Weights:
1.234 pounds for pouch sizes below (Flexible, Lumen, and Non-Lumen Cycles)
300 x 450 mm
250 x 400 mm
190 x 330 mm

.122 pounds for pouch sizes below (Flexible and Lumen Cycles)
130 x 380 mm
130 x 270 mm
90 x 250 mm
90 x 200 mm

.204 pounds for pouch sizes below (Non-Lumen Cycle)
130 x 380 mm
130 x 270 mm
90 x 250 mm
90 x 200 mm

Pouch Sizes:
300 x 450 mm
250 x 400 mm

190 x 330 mm
130 x 380 mm
130 x 270 mm
90 x 250 mm
90 x 200 mm

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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K231996
510(k) Summary (in accordance with 21CFR807.92)

510K Summary Elements per 21CFR807.92	Summary
Submitter's name, address, telephone number, a contact person, and the date the summary was prepared	Wipak Oy Wipaktie 2 Nastola Finland Contact: Hanna Marttila Phone: +358 (0)40 124 0290 Date prepared: September 6, 2023 Submitter: Amanda Singleton, Compliance Systems International, 716.440.7364
Name of the device including the trade or proprietary name if applicable **Common or usual name** **Classification name** **Classification Product Code** **Device Classification** **Regulation Number**	Proprietary Name: Steriking® LT-Blueline Pouches with Tyvek® Common Name: Peel Pouch Classification Name: Sterilization wrap FRG Class II 21 CFR 880.6850
Identification of the legally marketed device to which the submitter claims equivalence (Primary Predicate device)	K221379 - Steriking® LT-Blueline Pouches with Tyvek®
Description of the device	Steriking® LT-Blueline Pouches with Tyvek® are intended to be used to contain medical devices to be terminally sterilized in the STERIS® V-Pro® Sterilization System. The medical devices are inserted into the Pouch, sealed, and then sterilized in the STERIS® V-Pro® Sterilization System. Sterilization Cycles are noted below. After completion of the sterilization process, the Pouch maintains sterility of the enclosed medical devices until the seal is opened. These pouches are made from a plastic film and Tyvek that is heat-sealed on three sides. The fourth side is left opened and will be self-sealed when used. Steriking® LT-Blueline Pouches with Tyvek® are intended to allow sterilization of enclosed devices and to maintain sterility of the enclosed devices until used up to 1 year post sterilization. The products are for single use only. The pouches are constructed from Tyvek®/plastic films. The self-sealed pouches are self sealed prior to processing in the STERIS® V-Pro® Sterilization Systems. Sterilization Systems: STERIS® V-Pro® Cycles: Lumen Non-Lumen Flexible

Indications for Use	Steriking® LT-Blueline Pouches with Tyvek® are intended to provide health care workers with an effective method to enclose devices intended for sterilization in the STERIS® V-Pro® Sterilizer Systems. The device is intended to allow sterilization of enclosed devices and to maintain sterility of the enclosed devices until used up to 1 year post sterilization. The products are for single use only. Steriking® LT-Blueline Pouches with Tyvek® are intended for use in the following STERIS® V-Pro® Sterilization Cycles: Lumen Cycle Non Lumen Cycle Flexible Cycle Device lumen dimensions: Flexible Cycle: 1 lumen max and 1 mm min ID x 1050 mm max length for all pouch sizes. Lumen Cycle: 1 lumen max for all pouch sizes. 1 mm min ID for pouch sizes: 130 x 380 mm, 130 x 270 mm, 90 x 250 mm, 90 x 200 mm 2 mm min ID for pouch sizes: 300 x 450 mm, 250 x 400 mm, 190 x 330 mm 125 mm max length for pouch sizes: 130 x 380 mm, 130 x 270 mm, 90 x 250 mm, 90 x 200 mm 250 mm max length for pouch sizes: 300 x 450 mm, 250 x 400 mm, 190 x 330 mm Max Weights: 1.234 pounds for pouch sizes below (Flexible, Lumen, and Non-Lumen Cycles) 300 x 450 mm 250 x 400 mm 190 x 330 mm .122 pounds for pouch sizes below (Flexible and Lumen Cycles) 130 x 380 mm 130 x 270 mm 90 x 250 mm 90 x 200 mm .204 pounds for pouch sizes below (Non-Lumen Cycle) 130 x 380 mm 130 x 270 mm 90 x 250 mm 90 x 200 mm Pouch Sizes: 300 x 450 mm 250 x 400 mm 190 x 330 mm 130 x 380 mm 130 x 270 mm

	90 x 250 mm 90 x 200 mm		
	Technological Characteristics Comparison Table		
	Submission Device – K231996 Steriking® LT-Blueline Pouches with Tyvek®	**Comparison**	**Primary Predicate Device –** K221379 - Steriking® LT-Blueline Pouches with Tyvek®
Device Classification	Class II	Same	Class II
Classification Name	Sterilization Wrap	Same	Sterilization Wrap
Regulation Name	21 CFR 880.6850	Same	21 CFR 880.6850
Product Code	FRG	Same	FRG
Indications for Use	Steriking® LT-Blueline Pouches with Tyvek® are intended to provide health care workers with an effective method to enclose devices intended for sterilization in the STERIS® V-Pro® Sterilizer Systems. The device is intended to allow sterilization of enclosed devices and to maintain sterility of the enclosed devices until used up to 1 year post sterilization. The products are for single use only. Steriking® LT-Blueline Pouches with Tyvek® are intended for use in the following STERIS® V-Pro® Sterilization Cycles: Lumen Cycle Non Lumen Cycle Flexible Cycle Device lumen dimensions: Flexible Cycle: 1 lumen max and 1 mm min ID x 1050 mm max length for all pouch sizes. Lumen Cycle: 1 lumen max for all pouch sizes. 1 mm min ID for pouch sizes: 130 x 380 mm, 130 x 270 mm, 90 x 250 mm, 90 x 200 mm 2 mm min ID for pouch sizes: 300 x 450 mm, 250 x 400 mm, 190 x 330 mm	Different	Steriking® LT-Blueline Pouches with Tyvek are intended to provide health care workers with an effective method to enclose devices intended for sterilization in the STERIS® V-PRO® Sterilizer Systems. The device is intended to allow sterilization of enclosed devices and to maintain sterility of the enclosed devices until used up to 3 years post sterilization. The products are for single use only. The Steriking® LT-Blueline Pouches with Tyvek® are intended for use in the following STERIS® V-PRO® Sterilization Cycles **:** Lumen Cycle Non Lumen Cycle Flex Cycle **Device lumen dimensions :** Flexible Cycle : 1 lumen x 1 mm min ID x 1050 mm max length for all pouch sizes. Lumen Cycle: 1 lumen x 1 mm min ID for all pouch sizes. For pouch sizes 250x500mm, 250x390mm, 205x390mm, max length of 125 mm. For all other pouch sizes, max length of 50 mm.

	125 mm max length for pouch sizes: 130 x 380 mm, 130 x 270 mm, 90 x 250 mm, 90 x 200 mm 250 mm max length for pouch sizes: 300 x 450 mm, 250 x 400 mm, 190 x 330 mm Max Weights: 1.234 pounds for pouch sizes below (Flexible, Lumen, and Non-Lumen Cycles) 300 x 450 mm 250 x 400 mm 190 x 330 mm .122 pounds for pouch sizes below (Flexible and Lumen Cycles) 130 x 380 mm 130 x 270 mm 90 x 250 mm 90 x 200 mm .204 pounds for pouch sizes below (Non-Lumen Cycle) 130 x 380 mm 130 x 270 mm 90 x 250 mm 90 x 200 mm Pouch Sizes: 300 x 450 mm 250 x 400 mm 190 x 330 mm 130 x 380 mm 130 x 270 mm 90 x 250 mm 90 x 200 mm		**Max Weights:** 1.410 pounds for pouch sizes below (Flexible, Lumen, and Non-Lumen Cycles) 250 mm x 500 mm 250 mm x 390 mm 205 mm x 390 mm .114 pounds for pouch sizes below (Flexible and Lumen Cycles) 160 mm x 600 mm 160 mm x 440 mm 150 mm x 300 mm 100 mm x 250 mm 75 mm x 200 mm .158 pounds for pouch sizes below (Non-Lumen Cycle) 160 mm x 600 mm 160 mm x 440 mm 150 mm x 300 mm 100 mm x 250 mm 75 mm x 200 mm **Flat Sterilization Pouch Sizes:** 75 x 200 mm 100x 250 mm 150 x 300 mm 160 x 440 mm 160 x 600 mm 205 x 390 mm 250 x 390 mm 250 x 500 mm
Design	These pouches are made from a plastic film and Tyvek that is heat sealed on three sides. The fourth side is left opened and will be self-sealed when used.	Different	These pouches are made from a plastic film and Tyvek that is heat sealed on three sides. The fourth side is left opened and will be heat-sealed when used.
Backing Material	Tyvek®	No Change	Tyvek®
Transparent Film	BOPET/PE	No Change	BOPET/PE
Sterilization Processes	H2O2 Sterilization Process as per: STERIS® V-Pro® Cycles: Lumen Non-Lumen	No Change	H2O2 Sterilization Process as per: STERIS® V-Pro® Cycles: Lumen Non-Lumen

<table>
<tr><td></td><td>Flex</td><td></td><td>Flex</td></tr>
<tr><td>Sterilant Validation</td><td>Achieved a 10^{-6} Sterility Assurance Level (SAL) of Geobacillus stearothermophilus.

STERIS® V-Pro® Cycles:
Lumen
Non-Lumen
Flex</td><td>No Change</td><td>Achieved a 10^{-6} Sterility Assurance Level (SAL) of Geobacillus stearothermophilus.

STERIS® V-Pro® Cycles:
Lumen
Non-Lumen
Flex</td></tr>
<tr><td>Package Integrity</td><td>Pass</td><td>No Change</td><td>Pass</td></tr>
<tr><td>Biocompatibility</td><td>Pass</td><td>No Change</td><td>Pass</td></tr>
<tr><td>Shelf-Life Pre-Sterilization</td><td>3 years</td><td>Different</td><td>5 years</td></tr>
<tr><td>Maintenance of Sterility</td><td>1 year</td><td>Different</td><td>3 years</td></tr>
<tr><td>Max weights</td><td>
<table>
<tr><th>Pouch size</th><th>Non-Lumen Cycle</th><th>Lumen Cycle</th><th>Flexible Cycle</th></tr>
<tr><td></td><td colspan="3">weight (pounds)</td></tr>
<tr><td>300 x 450 mm</td><td>1.234</td><td>1.234</td><td>1.234</td></tr>
<tr><td>250 x 400 mm</td><td>1.234</td><td>1.234</td><td>1.234</td></tr>
<tr><td>190 x 330 mm</td><td>1.234</td><td>1.234</td><td>1.234</td></tr>
<tr><td>130 x 380 mm</td><td>0.122</td><td>0.204</td><td>0.122</td></tr>
<tr><td>130 x 270 mm</td><td>0.122</td><td>0.204</td><td>0.122</td></tr>
<tr><td>90 x 250 mm</td><td>0.122</td><td>0.204</td><td>0.122</td></tr>
<tr><td>90 x 200 mm</td><td>0.122</td><td>0.204</td><td>0.122</td></tr>
</table>
</td><td>Different</td><td>
<table>
<tr><th>Pouch size</th><th>Flexible Cycle</th><th>Lumen Cycle</th><th>Non-Lumen Cycle</th></tr>
<tr><td></td><td colspan="3">max weight (pounds)</td></tr>
<tr><td>250 x 500 mm</td><td>1.410</td><td>1.410</td><td>1.410</td></tr>
<tr><td>250 x 390 mm</td><td>1.410</td><td>1.410</td><td>1.410</td></tr>
<tr><td>205 x 390 mm</td><td>1.410</td><td>1.410</td><td>1.410</td></tr>
<tr><td>160 x 600 mm</td><td>0.114</td><td>0.114</td><td>0.158</td></tr>
<tr><td>160 x 440 mm</td><td>0.114</td><td>0.114</td><td>0.158</td></tr>
<tr><td>150 x 300 mm</td><td>0.114</td><td>0.114</td><td>0.158</td></tr>
<tr><td>100 x 250 mm</td><td>0.114</td><td>0.114</td><td>0.158</td></tr>
<tr><td>75 x 200 mm</td><td>0.114</td><td>0.114</td><td>0.158</td></tr>
</table>
</td></tr>
<tr><td>Max Lumen Dimensions</td><td>Flexible Cycle:
1 lumen max and 1 mm min ID x 1050 mm max length for all pouch sizes.

Lumen Cycle: 1 lumen max for all pouch sizes.
1 mm min ID for pouch sizes: 130 x 380 mm, 130 x 270 mm, 90 x 250 mm, 90 x 200 mm

2 mm min ID for pouch sizes: 300 x 450 mm, 250 x 400 mm, 190 x 330 mm

125 mm max length for pouch sizes: 130 x 380 mm, 130 x 270 mm, 90 x 250 mm, 90 x 200 mm

250 mm max length for pouch sizes: 300 x 450 mm, 250 x 400</td><td>Different</td><td>Flexible Cycle:
1 lumen x 1 mm min ID x 1050 mm max length for all pouch sizes.

Lumen Cycle:
1 lumen x 1 mm min ID for all pouch sizes.
For pouch sizes 250x500mm, 250x390mm, 205x390mm, max length of 125 mm.
For all other pouch sizes, max length of 50 mm.</td></tr>
</table>

	mm, 190 x 330 mm		

Performance Data:

Cycle	Test Category	Test	Sample Type	Standard/Spec	FDA Recognition number	Acceptance Criteria	Result Summary	Conclusion
NA	Package Integrity, Pre-Sterilization Shelf Life	Dye Migration	Unsterilized-Aged	ASTM F1929	14-484	No leaks detected after dye migration	Passed dye penetration at time zero	**Pass**
NA	Package Integrity, Pre-Sterilization Shelf Life	Tensile	Unsterilized-Aged	ASTM F88-05 AAMI TIR12:2010 AAMI/ISO TIR16775:2014 ISO 11607	14-482 14-530	All samples are > 1.5N/15mm per ASTM F88	All samples are > 1.5N/15mm per ASTM F88	**Pass**
Lumen Cycle	Sterilization Penetration	Sterilization Penetration	Sterilized-Unaged	AAMI TIR12:2010 ANSI/AAMI ST79 ANSI/AAMI/ISO 14937:2009 ANSI/AAMI/ISO 17664:2017	14-511 14-337 14-515	Demonstrating that a minimum of 1.0x10^6 Geobacilus stearothermophilus spores were killed in a half-cycle (6-log reduction) using a worst-case, end of shelf-life injection volume	Negative for growth following the minimum incubation period	**Pass**
Non-Lumen Cycle	Sterilization Penetration	Sterilization Penetration	Sterilized-Unaged	AAMI TIR12:2010 ANSI/AAMI ST79 ANSI/AAMI/ISO 14937:2009 ANSI/AAMI/ISO 17664:2017	14-511 14-337 14-515	Demonstrating that a minimum of 1.0x10^6 Geobacilus stearothermophilus spores were killed in a half-cycle (6-log reduction) using a worst-case, end of shelf-life injection volume	Negative for growth following the minimum incubation period	**Pass**

Flexible Cycle	Sterilization Penetration	Sterilization Penetration	Sterilized-Unaged	AAMI TIR12:2010 ANSI/AAMI ST79 ANSI/AAMI/ISO 14937:2009 ANSI/AAMI/ISO 17664:2017	14-511 14-337 14-515	Demonstrating that a minimum of 1.0x10^6 Geobacilus stearothermophilus spores were killed in a half-cycle (6-log reduction) using a worst-case, end of shelf-life injection volume	Negative for growth following the minimum incubation period	**Pass**
Lumen Cycle	Package Integrity, Post-Sterilization	Tensile	Sterilized-Unaged	ASTM F88-05 AAMI TIR12:2010 AAMI/ISO TIR16775:2014 ISO 11607	14-482 14-530	All samples are > 1.5N/15mm per ASTM F88	All samples are > 1.5N/15mm per ASTM F88	**Pass**
Lumen Cycle	Biocompatibility	Cytotoxicity	Sterilized-Unaged	ISO 10993-5 ISO 10993-12 ISO 11607-1	14-530 2-245 2-289	No signs of cellular growth	Negative for growth following the minimum incubation period	**Pass**
Lumen Cycle	Package Integrity, Post-Sterilization	Microbial Aerosol Challenge	Sterilized-Unaged	AAMI TIR12:2010 ANSI/AAMI ST79:2017	14-511	A sample which demonstrates that all items remain sterile following exposure	Each pouch met the sterility maintenance requirement as there was no growth in any of the culture tubes containing the stainless-steel coupons at the end if the incubation period.	**Pass**
Lumen Cycle	Post Sterilization Shelf Life	Maintenance of Sterility	Sterilized and Aged (365 days)	AAMI TIR12:2010 ANSI/AAMI ST79:2017 ISO 11607-1 ANSI/AAMI/ISO 14937	14-511 14-530 14-337	No growth after exposure	Pass No growth following exposure	**Pass**
Lumen Cycle	Package Integrity, Post-Sterilization	Accelerated Aging	Sterilized and Aged (3 years accelerated aging)	ANSI/AAMI ST8:2013/(R)2018 AAMI TIR12:2010	14-406 14-396 14-511 14-530 14-497	Seal maintains integrity	Pass No suspect seals were observed, and the test	**Pass**

				ANSI/AAMI ST77:2017 ANSI/AAMI ST79:2017 ISO 11607-1 ASTM F1980			samples remained intact.	
Lumen Cycle	Package Integrity, Post-Sterilization	Tensile	Sterilized and Aged (3 years accelerated aging)	ASTM F88 AAMI TIR12:2010 AAMI/ISO TIR16775:2014 ISO 11607	14-482 14-530	All samples are > 1.5N/15mm per ASTM F88	All samples are > 1.5N/15mm per ASTM F88	**Pass**

Non-Clinical Testing Conclusion:

The conclusions drawn from the non-clinical tests demonstrate that the proposed device is as safe, as effective, and performs as well as or better than the predicate device K221379.

Discussion:

Any differences between the predicate's and the proposed device's performance testing has no impact on the impact the safety or effectiveness of the subject device. The modification of the Steriking Blueline Pouch with Tyvek from its predicate is the addition of an adhesive strip to seal the pouch. The addition of an adhesive strip allows the user to close the pouch quickly and securely, without the use of heat-sealing equipment.

The Tyvek and BOPET materials used to make the proposed self seal pouch are identical to the materials used to make the predicate heat-seal pouch. The plastic film and Tyvek are sealed together with heat and then the web is cut to specific lengths during the assembly process for both the heat-sealed and self-sealed pouches. The fourth side is left open and is sealed when used. The Tyvek material and the film are not modified during the construction of pouches.

The proposed self seal pouches have undergone the same testing as the predicate heat seal pouches, including Sterilization Penetration, Sterility Maintenance, and Package Integrity. The self-seal pouch allows for devices to be sterilized, and sterility to be maintained. Studies on the self-seal pouch were performed concurrently to the heat-seal pouch studies.

Self-seal pouches have also undergone Cytotoxicity testing following Sterilization. Studies were executed in the same manner as the heat-seal predicate device. The proposed self seal pouch was determined not to have a cytotoxic effect.

Differences in validated loads, count of lumens, length of lumens, and inner diameter (ID) of lumens is a result of the pouch sizes differing from the heat sealed and self sealed pouches.

Instructions for Self-Sealing the pouch are noted in the Instructions for Use.

Conclusion:

The conclusions drawn from the non-clinical tests demonstrate that the proposed device is as safe, as effective, and performs as well as or better than the predicate device K221379.