



December 22, 2022

Wipak OY  
% Amanda Singleton  
Consultant  
Compliance Systems International  
53 Assembly Drive, Unit 149  
Mendon, New York 14506

Re: K221377

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: November 29, 2022  
Received: November 29, 2022

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](mailto:DICE@fda.hhs.gov)) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Anne D. Talley -S

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

## Indications for Use

510(k) Number (if known)

K221377

Device Name

SteriKing® LT Blueline Pouch with Tyvek®

Indications for Use (Describe)

The SteriKing® LT Blueline with Tyvek® pouches are intended to provide health care workers with an effective method to enclose devices intended for sterilization in the STERRAD® 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 with Tyvek® pouches are intended for use in the following STERRAD® Sterilization Cycles:

NX Standard  
NX Advanced  
100NX Duo  
100NX Flex  
100NX Standard

Max weights:

NX Standard Cycle:

75 mm x 200 mm, 100 mm x 250 mm, 150 mm x 300 mm, 160 mm x 440 mm, 160 mm x 600 mm: .088 pounds  
205 mm x 390 mm, 250 mm x 390 mm, 250 mm x 500 mm: 1.382 pounds

NX Advanced Cycle:

75 mm x 200 mm, 100 mm x 250 mm, 150 mm x 300 mm, 160 mm x 440 mm, 160 mm x 600 mm: .084 pounds  
205 mm x 390 mm, 250 mm x 390 mm, 250 mm x 500 mm: 1.393 pounds

100NX Duo Cycle:

75 mm x 200 mm, 100 mm x 250 mm, 150 mm x 300 mm, 160 mm x 440 mm, 160 mm x 600 mm: .104 pounds  
205 mm x 390 mm, 250 mm x 390 mm, 250 mm x 500 mm: 1.400 pounds

100NX Flex Cycle:

75 mm x 200 mm, 100 mm x 250 mm, 150 mm x 300 mm, 160 mm x 440 mm, 160 mm x 600 mm: .158 pounds  
205 mm x 390 mm, 250 mm x 390 mm, 250 mm x 500 mm: 1.400 pounds

100NX Standard Cycle:

75 mm x 200 mm, 100 mm x 250 mm, 150 mm x 300 mm, 160 mm x 440 mm, 160 mm x 600 mm: .158 pounds  
205 mm x 390 mm, 250 mm x 390 mm, 250 mm x 500 mm: 4.476 pounds

Max lumens:

1 mm min ID and 1 max lumen for all cycles

NX Standard Cycle: For pouch sizes 250x500mm, 250x390mm, 205x390mm is 125 mm max length. Max length is 50 mm for all other pouch sizes.

---

NX Advanced Cycle: For pouch sizes 250x500mm, 250x390mm, 205x390mm is 125 mm max length. Max length is 50 mm for all other pouch sizes.

100NX Duo Cycle: For pouch sizes 250x500mm, 250x390mm, 205x390mm is 875 mm max length. Max length is 850 mm for all other pouch sizes.

100NX Flex Cycle: Max length is 850 mm for all pouch sizes.

100NX Standard Cycle: For pouch sizes 250x500mm, 250x390mm, 205x390mm is 125 mm max length. Max length is 50 mm for all other pouch sizes.

Pouch Sizes:

250 mm x 500 mm

250 mm x 390 mm

205 mm x 390 mm

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

---

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.

**\*DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.\***

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services  
Food and Drug Administration  
Office of Chief Information Officer  
Paperwork Reduction Act (PRA) Staff  
[PRASStaff@fda.hhs.gov](mailto:PRASStaff@fda.hhs.gov)

*"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."*

**510K Summary (in accordance with 21CFR807.92)**

<p><b>510K Summary Elements per 21CFR807.92</b></p>	<p><b>Summary</b></p>
<p><b>Submitter's name, address, telephone number, a contact person, and the date the summary was prepared</b></p>	<p>Wipak Oy                  Wipaktie 2                  Nastola Finland                  Contact: Hanna Marttila Phone: +358 (0)40 124 0290                  Date prepared: December 21, 2022                  Consultant: Amanda Singleton, CSI LLC. Phone: 716.4407364</p>
<p><b>Name of the device including the trade or proprietary name if applicable</b></p> <p><b>Common or usual name</b></p> <p><b>Classification name</b></p> <p><b>Classification Product Code</b></p> <p><b>Device Classification</b></p> <p><b>Regulation Number</b></p>	<p>Proprietary Name: Steriking® LT-Blueline Pouches with Tyvek®</p> <p>Common Name: Peel Pouch</p> <p>Classification Name: Sterilization wrap</p> <p>FRG</p> <p>Class II</p> <p>21 CFR 880.6850</p>
<p><b>Identification of the legally marketed device to which the submitter claims equivalence (Predicate device)</b></p>	<p>K180672, Sterilization Pouch/Roll Made With Tyvek®</p>
<p><b>Description of the device</b></p>	<p>Steriking® LT-Blueline Pouches with Tyvek® are intended to be used to contain medical devices to be terminally sterilized in the STERRAD® Sterilization System. The medical devices are inserted into the Pouch, sealed, and then sterilized in the STERRAD® 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 heat-sealed when used.</p> <p>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 3 years post sterilization. The products are for single use only.</p> <p>The pouches are constructed from Tyvek®/plastic films. The heat-sealed pouches are heat sealed prior to processing in the STERRAD® Sterilization Systems.</p> <p>Sterilization Systems:</p> <p>STERRAD® Cycles:                  NX Standard                  NX Advanced                  100NX Duo                  100NX Flex                  100NX Standard</p>

<p><b>Intended use of the device</b></p>	<p>The 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 STERRAD® Sterilizer Systems.</p> <p>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.</p>		
<p><b>Technological characteristics compared to predicate (as follows)</b></p>	<p>See below as follows:</p>		
<p><b>Discussion of nonclinical tests submitted, referenced, or utilized in the premarket notification submission for a determination of substantial equivalence</b></p>	<p><b>Submission Device –</b> Steriking® LT-Blueline Pouches with Tyvek®</p>	<p><b>SE Determination</b></p>	<p><b>Predicate Device –</b> K180672 - Sterilization Pouch/Roll Made With Tyvek</p>
<p><b>Indications for Use</b></p>	<p>The SteriKing® LT Blueline with Tyvek® pouches are intended to provide health care workers with an effective method to enclose devices intended for sterilization in the STERRAD® Sterilizer Systems.</p> <p>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.</p> <p>The SteriKing® LT Blueline with Tyvek® pouches are intended for use in the following STERRAD® Sterilization Cycles:</p> <p>NX Standard NX Advanced 100NX Duo 100NX Flex 100NX Standard</p> <p>Max weights: <b>NX Standard Cycle:</b> 75 mm x 200 mm, 100 mm x 250 mm, 150 mm x 300 mm, 160 mm x 440 mm, 160 mm x 600 mm: .088 pounds</p> <p>205 mm x 390 mm, 250 mm x</p> <p>Similar</p> <p>The Sterilization Pouch/Roll Made with Tyvek® are intended to provide health care workers with an effective method to enclose devices intended for sterilization in the STERRAD® 100S Sterilizer. The device is intended to allow sterilization of enclosed devices and also to maintain sterility of the enclosed devices until used up to 3 years post sterilization. The pouches and rolls are printed with a chemical indicator bar which is a process indicator (ISO 11140-1:2005) that changes from red to blue (or lighter) when exposed to hydrogen peroxide vapor during processing in the STERRAD® Sterilizer. The Sterilization Pouch/Roll Made with Tyvek® is offered in the follow 5 types: Self-sealing sterilization pouches Sterilization pouches, Flat Sterilization pouches, Gusseted Sterilization</p>		

	<p>390 mm, 250 mm x 500 mm: 1.382 pounds</p> <p><b>NX Advanced Cycle:</b> 75 mm x 200 mm, 100 mm x 250 mm, 150 mm x 300 mm, 160 mm x 440 mm, 160 mm x 600 mm: .084 pounds</p> <p>205 mm x 390 mm, 250 mm x 390 mm, 250 mm x 500 mm: 1.393 pounds</p> <p><b>100NX Duo Cycle:</b> 75 mm x 200 mm, 100 mm x 250 mm, 150 mm x 300 mm, 160 mm x 440 mm, 160 mm x 600 mm: .104 pounds</p> <p>205 mm x 390 mm, 250 mm x 390 mm, 250 mm x 500 mm: 1.400 pounds</p> <p><b>100NX Flex Cycle:</b> 75 mm x 200 mm, 100 mm x 250 mm, 150 mm x 300 mm, 160 mm x 440 mm, 160 mm x 600 mm: .158 pounds</p> <p>205 mm x 390 mm, 250 mm x 390 mm, 250 mm x 500 mm: 1.400 pounds</p> <p><b>100NX Standard Cycle:</b> 75 mm x 200 mm, 100 mm x 250 mm, 150 mm x 300 mm, 160 mm x 440 mm, 160 mm x 600 mm: .158 pounds</p> <p>205 mm x 390 mm, 250 mm x 390 mm, 250 mm x 500 mm: 4.476 pounds</p> <p>Max lumens: 1 mm min ID and Max 1 lumen. for all cycles</p> <p><b>NX Standard Cycle:</b> For pouch sizes 250x500mm, 250x390mm, 205x390mm is 125 mm max length. Max length is 50 mm for all other pouch sizes.</p>		rolls, Flat Sterilization rolls, Gusseted
--	---	--	---

	<p><b>NX Advanced Cycle:</b> For pouch sizes 250x500mm, 250x390mm, 205x390mm is 125 mm max length. Max length is 50 mm for all other pouch sizes.</p> <p><b>100NX Duo Cycle:</b> For pouch sizes 250x500mm, 250x390mm, 205x390mm is 875 mm max length. Max length is 850 mm for all other pouch sizes.</p> <p><b>100NX Flex Cycle:</b> Max length is 850 mm for all pouch sizes.</p> <p><b>100NX Standard Cycle:</b> For pouch sizes 250x500mm, 250x390mm, 205x390mm is 125 mm max length. Max length is 50 mm for all other pouch sizes.</p> <p>Pouch Sizes: 250 mm x 500 mm 250 mm x 390 mm 205 mm x 390 mm 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</p>		
<b>Design</b>	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.	Same	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.
<b>Backing Material</b>	Tyvek®	Same	Tyvek®
<b>Transparent Film</b>	BOPET/PE	Similar	PE
<b>Sterilization Processes</b>	H <sub>2</sub> O <sub>2</sub> Sterilization Process as per: <b>STERRAD®</b> NX Standard NX Advanced 100NX Duo 100NX Flex 100NX Standard	Similar	STERRAD® 100S
<b>Sterilant Validation</b>	Achieved a 10 <sup>-6</sup> Sterility Assurance Level (SAL) of Geobacillus	Similar	Showed a 6 log reduction of Geobacillus



AAMI TIR12:2010 ANSI/AAMI ST79 ANSI/AAMI/ISO 14937:2009 ANSI/AAMI/ISO 17664:2017	stearothermophilus.  NX Standard NX Advanced 100NX Duo 100NX Flex 100NX Standard		stearothermophilus
<b>Dye Migration</b>  ISO 11607 ASTM F1929 AAMI TIR12:2010	No leaks detected after dye migration	Same	No leaks detected after dye migration
<b>Seal Strength</b>  ASTM F88 AAMI TIR12:2010 AAMI/ISO TIR16775:2014 ISO 11607	> 1.5N/15mm per ASTM F88	Same	> 1.5N/15mm per ASTM F88
<b>Microbial Barrier Properties</b>  ISO 11607-1 AAMI TIR12:2010 ANSI/AAMI ST79:2017	Pass  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 of the incubation period.	Similar	Pass
<b>Biocompatibility</b>	Pass ISO 10993-5	Similar	Pass ISO 10993-12
<b>Shelf-Life Pre-Sterilization</b>  ASTM F1929-15 ASTM F88	5 years	Similar	3 years
<b>Maintenance of Sterility – Accelerated Aging</b>  ANSI/AAMI ST8:2013/(R)2018 AAMI TIR12:2010 ANSI/AAMI ST77:2017 ANSI/AAMI ST79:2017 ISO 11607-1 ASTM F1980 ASTM F1929-15 ASTM F88	3 years	Same	3 years

Dimensions and max load weight	Pouch size	NX Advanced Cycle	NX Standard Cycle	100NX Duo Cycle	100NX Flex Cycle	100NX Standard Cycle	Similar	Not listed
	weight (pounds)							
	250 x 500 mm	1.393	1.382	1.400	1.400	4.476		
	250 x 390 mm	1.393	1.382	1.400	1.400	4.476		
	205 x 390 mm	1.393	1.382	1.400	1.400	4.476		
	160 x 600 mm	0.084	0.088	0.104	0.158	0.158		
	160 x 440 mm	0.084	0.088	0.104	0.158	0.158		
	150 x 300 mm	0.084	0.088	0.104	0.158	0.158		
	100 x 250 mm	0.084	0.088	0.104	0.158	0.158		
	75 x 200 mm	0.084	0.088	0.104	0.158	0.158		
<b>Max Lumen Dimensions</b>	<p>1 mm min ID Lumen and Max 1 lumen for all cycles</p> <p>For NX Standard Cycle: For pouch sizes 250x500mm, 250x390mm, 205x390mm is 125 mm max length. Max length is 50 mm for all other pouch sizes.</p> <p>NX Advanced Cycle: For pouch sizes 250x500mm, 250x390mm, 205x390mm is 125 mm max length. Max length is 50 mm for all other pouch sizes.</p> <p>100NX Duo Cycle: For pouch sizes 250x500mm, 250x390mm, 205x390mm is 875 mm max length. Max length is 850 mm for all other pouch sizes.</p> <p>100NX Flex Cycle: Max length is 850 mm for all pouch sizes.</p> <p>100NX Standard Cycle: For pouch sizes 250x500mm, 250x390mm, 205x390mm is 125 mm max length. Max length is 50 mm for all other pouch sizes.</p>						Different	Not listed

**Summary of Non-Clinical Testing**

The Steriking® LT-Blueline Pouches with Tyvek® (submission device) has the identical intended use and indications for use as

the predicate devices. The subject device was compared to the predicate device by testing the Sterilant Penetration, Biocompatibility, Package Integrity, Material Compatibility, and Sterility Maintenance. The results of the Steriking® LT-Blueline Pouches with Tyvek® validation studies demonstrate that the sterilization pouches perform as intended. The results are summarized as follows:

- The Sterilant Penetration testing performed as described in AAMI / ANSI / ISO 14937:2009, “Sterilization of Health Care Products – General Requirements for Characterization of a Sterilizing Agent and the Development, Validation, and Routine Control of a Sterilization Process for Medical Devices”. The results confirm that the

sterilant is able to penetrate Steriking® LT-Blueline Pouches with Tyvek® and sustain direct contact with the medical instrument inside the subject device.

- The Biocompatibility testing performed as described in ISO 10993-5, Biological evaluation of medical devices — Part 5: Tests for in vitro cytotoxicity. The testing results demonstrate the Steriking® LT-Blueline Pouches with Tyvek® did not elicit any cytotoxic effect.
- The Package Integrity, Material Compatibility, Sterility Maintenance, and Microbial Aerosol Challenge testing was performed as described in ISO 11607. The use of the aerosol challenge test to analyze the microbial barrier properties of the samples was considered to be rigorous. By exposing the sealed test samples' exterior with aerosolized spores, the permeability of the samples to microorganisms was challenged. A sample which demonstrates that all items remain sterile following this test is considered safe and effective at maintaining package integrity. The use of stainless-steel coupons was based on several considerations. First, they offer a convenient way to identify specific pieces to be sterility tested and to confirm that samples were indeed placed in the specified locations. Second, coupons are relatively easy to manipulate, and reduces the likelihood of the introduction of adventitious growth into the sterility test results. Finally, the coupons are comprised of metals consistent with metals used to manufacture medical instruments.
- The Microbial Aerosol Challenge study is a whole package test which challenges all aspects of the pouch in its final state. Conversely the ISO 11607 tests (Dye Migration and Seal Peel) test only one component of the pouch at time as it is not a whole package test. The Microbial Aerosol Challenge is a rigorous whole package test, and therefore the results are more comprehensive and supersede the results from Dye Migration and Seal Peel tests.

Test Methodology	Purpose	Acceptance Criteria	Results
ISO 10993-5 Biological Evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity	Biocompatibility	no reduction of cell growth or cell lysis was observed	Pass
AAMI TIR12:2010 - Designing, testing, and labeling reusable medical devices for reprocessing in health care facilities	Sterilant Penetration	Demonstrating that a minimum of 1.0x10 <sup>6</sup> Geobacillus stearothermophilus spores were killed in a half-cycle (6-log reduction)	Pass Negative for growth
ASTM F1929-15: Standard test method for detecting seal leaks in porous medical packaging by dye migration	Package Integrity	Dye Penetration: none	Pass
ANSI/AAMI ST79:2017 - Comprehensive guide to steam sterilization and sterility assurance in health care facilities  AAMI TIR12:2010 - Designing, testing, and labeling reusable medical devices for reprocessing in health care facilities	Microbial Barrier Properties	A sample which demonstrates that all items remain sterile following exposure	Pass  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 of the incubation period.
ASTM F1929-15: Standard test method for detecting seal leaks in porous medical packaging by dye migration	Shelf Life <b>Pre</b> Sterilization	Dye Penetration: none Seal peel: =/>1.5N/15mm	Pass

<p>ASTM F88: Standard Test Method for Seal Strength of Flexible Barrier Materials</p>			
<p>ASTM F1980 – 16 Standard Guide for Accelerated Aging of Sterile Barrier Systems for Medical Devices</p> <p>ASTM F1929-15: Standard test method for detecting seal leaks in porous medical packaging by dye migration</p> <p>ASTM F88: Standard Test Method for Seal Strength of Flexible Barrier Materials</p>	<p>Shelf Life <b>Post</b> Sterilization</p>	<p>Dye Penetration: none Seal peel: <math>\neq &gt; 1.5N/15mm</math></p>	<p>Pass</p>
<ol style="list-style-type: none"> <li>1. ASTM F1608, ASTM F2638 - Microbial Barrier</li> <li>2. ASTM D3776 - Basis Weight of Tyvek</li> <li>3. ASTM D2724 - Delamination of Tyvek</li> <li>4. TAPPI T460 - Gurly Hill porosity of Tyvek</li> <li>5. ISO 1924-2 - Tensile Strength, MD of Tyvek</li> <li>6. ISO 1924-2 - Elongation, MD of Tyvek</li> <li>7. ASTM D1424 - Elmendorf Tear, MD of Tyvek</li> <li>8. ISO 534 - Thickness of Tyvek</li> <li>9. ISO 5636-3 - Bendtsen air permeability of Tyvek</li> <li>10. TAPPI T523 - Moisture vapor transmission Rate of Tyvek</li> <li>11. ISO 2758 - Mullen, burst of Tyvek</li> <li>12. ASTM D3420 - Spencer puncture of Tyvek</li> </ol>	<p>Material Compatibility</p>	<p>Meets specifications per Technical Data Sheets. Included in Bench Testing Summary.</p>	<p>Pass</p>

**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 K180672.