January 4, 2023

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

Re: K221379
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: December 27, 2022
Received: December 27, 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) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Colin O'neill -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

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K221379

Device Name
Steriking® LT-Blueline Pouches with Tyvek®

Indications for Use *(Describe)*

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 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
Flexible 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.

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

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.

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5. 510K 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 Contacts: Hanna Marttila Phone: +358 (0)40 124 0290 Consultant: Amanda Singleton, CSI LLC. Phone: 716.4407364 53 Assembly Drive, Unit 149, Mendon, NY 14506 Date prepared: January 4, 2023
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)	K180672, Sterilization Pouch/Roll Made 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® Sterilization System. The medical devices are inserted into the Pouch, sealed, and then sterilized in the STERIS® 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. 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. The pouches are constructed from Tyvek®/plastic films. The heat-sealed pouches are heat sealed prior to processing in the STERIS® V-PRO® Sterilization Systems. Sterilization Systems: **STERIS® V-PRO® Cycles:** Lumen Cycle, Non Lumen Cycle

	Flexible Cycle		
Intended use of the device	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 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.		
Technological characteristics compared to predicate (as follows)	See below as follows:		
Discussion of nonclinical tests submitted, referenced, or utilized in the premarket notification submission for a determination of substantial equivalence	**Submission Device** – Steriking® LT-Blueline Pouches with Tyvek®	**SE Determination**	**Predicate Device –** K180672 - Sterilization Pouch/Roll Made With Tyvek
Indications for Use	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 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 Flexible 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	Similar	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® 100S 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 rolls, Flat Sterilization rolls, Gusseted

	mm. For all other pouch sizes, max length of 50 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 heat-sealed when used.	Same	These pouches are made from a medical grade plastic film that is heat sealed on three sides. The fourth side is left opened and will be heat-sealed when used.
Backing Material	Tyvek®	Same	Tyvek®
Transparent Film	BOPET/PE	Same	PE
Sterilization Processes	H_2O_2 Sterilization Process as per: STERIS® V-PRO® Lumen Cycle Non-Lumen Cycle	Similar	H_2O_2 Sterilization Process as per: STERRAD® 100S

	Flexible Cycle		
Sterilant Validation AAMI TIR12:2010 ANSI/AAMI ST79 ANSI/AAMI/ISO 14937:2009 ANSI/AAMI/ISO 17664:2017	Achieved a 10^{-6} Sterility Assurance Level (SAL) of Geobacillus stearothermophilus. V-Pro® MAX and Max 2 Flexible Cycle V-Pro® 1 Plus Lumen Cycle V-Pro® 1 Plus Non-Lumen Cycle	Similar	Showed a 6 log reduction of Geobacillus stearothermophilus.
Dye Migration ISO 11607 ASTM F1929 AAMI TIR12:2010	No leaks detected after dye migration	Same	No leaks detected after dye migration
Seal Strength ASTM F88 AAMI TIR12:2010 AAMI/ISO TIR16775:2014 ISO 11607	> 1.5N/15mm per ASTM F88	Same	> 1.5N/15mm per ASTM F88
Microbial Barrier Properties 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
Biocompatibility	Pass ISO 10993-5	Similar	Pass ISO 10993-12
Shelf-Life Pre-Sterilization ASTM F1929-15 ASTM F88	5 years	Similar	3 years
Maintenance of Sterility – Accelerated Aging 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

<table>
<tr>
<td>Dimensions and max load weight</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>
<td>Similar</td>
<td>Not Listed</td>
</tr>
<tr>
<td>Max Lumen Dimensions</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>
<td>Different</td>
<td>Not Listed</td>
</tr>
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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.

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 1.0x10^6 Geobacilus 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 if the incubation period.
ASTM F1929-15: Standard test method for detecting seal leaks in porous medical packaging by dye migration ASTM F88: Standard Test Method for Seal Strength of Flexible Barrier Materials	Shelf Life **Pre** Sterilization	Dye Penetration: none Seal peel: =/>1.5N/15mm	Pass
ASTM F1980 − 16 Standard Guide for Accelerated Aging of Sterile Barrier Systems for Medical Devices ASTM F1929-15: Standard test method for detecting seal leaks in porous medical packaging by dye migration ASTM F88: Standard Test Method for Seal Strength of Flexible Barrier Materials	Shelf Life **Post** Sterilization	Dye Penetration: none Seal peel: =/>1.5N/15mm	Pass

1. ASTM F1608, ASTM F2638 - Microbial Barrier 2. ASTM D3776 - Basis Weight of Tyvek 3. ASTM D2724 - Delamination of Tyvek 4. TAPPI T460 - Gurly Hill porosity of Tyvek 5. ISO 1924-2 - Tensile Strength, MD of Tyvek 6. ISO 1924-2 - Elongation, MD of Tyvek 7. ASTM D1424 - Elmendorf Tear, MD of Tyvek 8. ISO 534 - Thickness of Tyvek 9. ISO 5636-3 - Bendtsen air permeability of Tyvek 10. TAPPI T523 - Moisture vapor transmission Rate of Tyvek 11. ISO 2758 - Mullen, burst of Tyvek 12. ASTM D3420 - Spencer puncture of Tyvek	Material Compatibility	Meets specifications per Technical Data Sheets. Included in Bench Testing Summary.	Pass

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.