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

September 7, 2023

Re: K231999
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 13:49:47 -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

Indications for Use

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

510(k) Number *(if known)*

K231999

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 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 1 years post sterilization. The products are for single use only. The Steriking® LT-Blueline Pouches with Tyvek 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:
For pouch sizes 90 x 200 mm, 90 x 250 mm, 130 x 270 mm, 130 x 380 mm, .094 lbs. For pouch sizes 190 x 330 mm, 250 x 400 mm, 300 x 450 mm, 1.194 pounds.

NX Advanced Cycle:
For pouch sizes 90 x 200 mm, 90 x 250 mm, 130 x 270 mm, 130 x 380 mm, .096 lbs. For pouch sizes 190 x 330 mm, 250 x 400 mm, 300 x 450 mm, 1.224 pounds.

100NX Duo Cycle:
For pouch sizes 90 x 200 mm, 90 x 250 mm, 130 x 270 mm, 130 x 380 mm, .116 lbs. For pouch sizes 190 x 330 mm, 250 x 400 mm, 300 x 450 mm, 1.222 pounds.

100NX Flex Cycle:
For pouch sizes 90 x 200 mm, 90 x 250 mm, 130 x 270 mm, 130 x 380 mm, .202 lbs. For pouch sizes 190 x 330 mm, 250 x 400 mm, 300 x 450 mm, 1.220 pounds.

100NX Standard Cycle:
For pouch sizes 90 x 200 mm, 90 x 250 mm, 130 x 270 mm, 130 x 380 mm, .202 lbs. For pouch sizes 190 x 330 mm, 250 x 400 mm, 300 x 450 mm, 4.478 pounds.

Max Count of lumens:
1 lumen max for All cycles

Max ID of lumens:

NX Standard Cycle:
1 mm ID for all pouch sizes

NX Advanced Cycle:
2 mm ID for all pouch sizes

100NX Cycle:
1 mm ID for all pouch sizes

100NX Flex Cycle:
1 mm ID for all pouch sizes

100NX Standard Cycle:
2 mm ID for all pouch sizes

Max lumen lengths:
NX Standard Cycle:
For pouch sizes 90 x 200 mm, 90 x 250 mm, 130 x 270 mm, 130 x 380 mm, 125 mm. For pouch sizes 190 x 330 mm, 250 x 400 mm, 300 x 450 mm, 250 mm.

NX Advanced Cycle:
For pouch sizes 90 x 200 mm, 90 x 250 mm, 130 x 270 mm, 130 x 380 mm, 125 mm. For pouch sizes 190 x 330 mm, 250 x 400 mm, 300 x 450 mm, 250 mm.

100NX Duo Cycle:
850 mm for all pouch sizes

100NX Flex Cycle:
850 mm for all pouch sizes

100NX Standard Cycle:
For pouch sizes 90 x 200 mm, 90 x 250 mm, 130 x 270 mm, 130 x 380 mm, 125 mm. For pouch sizes 190 x 330 mm, 250 x 400 mm, 300 x 450 mm, 250 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.

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
PRAStaff@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."

K231999
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	Proprietary Name: Steriking® LT-Blueline Pouches with Tyvek®
Common or usual name	Common Name: Peel Pouch
Classification name	Classification Name: Sterilization wrap
Classification Product Code **Device Classification** **Regulation Number**	FRG Class II 21 CFR 880.6850
Identification of the legally marketed device to which the submitter claims equivalence (Primary Predicate device)	K221377 -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 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 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 STERRAD® Sterilization Systems. Sterilization Systems: STERRAD® Cycles: NX Standard NX Advanced 100NX Duo 100NX Flex 100NX Standard

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 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 1 years post sterilization. The products are for single use only. The Steriking® LT-Blueline Pouches with Tyvek 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: For pouch sizes 90 x 200 mm, 90 x 250 mm, 130 x 270 mm, 130 x 380 mm, .094 lbs. For pouch sizes 190 x 330 mm, 250 x 400 mm, 300 x 450 mm, 1.194 pounds. NX Advanced Cycle: For pouch sizes 90 x 200 mm, 90 x 250 mm, 130 x 270 mm, 130 x 380 mm, .096 lbs. For pouch sizes 190 x 330 mm, 250 x 400 mm, 300 x 450 mm, 1.224 pounds. 100NX Duo Cycle: For pouch sizes 90 x 200 mm, 90 x 250 mm, 130 x 270 mm, 130 x 380 mm, .116 lbs. For pouch sizes 190 x 330 mm, 250 x 400 mm, 300 x 450 mm, 1.222 pounds. 100NX Flex Cycle: For pouch sizes 90 x 200 mm, 90 x 250 mm, 130 x 270 mm, 130 x 380 mm, .202 lbs. For pouch sizes 190 x 330 mm, 250 x 400 mm, 300 x 450 mm, 1.220 pounds. 100NX Standard Cycle: For pouch sizes 90 x 200 mm, 90 x 250 mm, 130 x 270 mm, 130 x 380 mm, .202 lbs. For pouch sizes 190 x 330 mm, 250 x 400 mm, 300 x 450 mm, 4.478 pounds. Max Count of lumens: 1 lumen max for All cycles Max ID of lumens: NX Standard Cycle: 1 mm ID for all pouch sizes NX Advanced Cycle: 2 mm ID for all pouch sizes 100NX Cycle: 1 mm ID for all pouch sizes

	100NX Flex Cycle: 1 mm ID for all pouch sizes 100NX Standard Cycle: 2 mm ID for all pouch sizes Max lumen lengths: NX Standard Cycle: For pouch sizes 90 x 200 mm, 90 x 250 mm, 130 x 270 mm, 130 x 380 mm, 125 mm. For pouch sizes 190 x 330 mm, 250 x 400 mm, 300 x 450 mm, 250 mm. NX Advanced Cycle: For pouch sizes 90 x 200 mm, 90 x 250 mm, 130 x 270 mm, 130 x 380 mm, 125 mm. For pouch sizes 190 x 330 mm, 250 x 400 mm, 300 x 450 mm, 250 mm. 100NX Duo Cycle: 850 mm for all pouch sizes 100NX Flex Cycle: 850 mm for all pouch sizes 100NX Standard Cycle: For pouch sizes 90 x 200 mm, 90 x 250 mm, 130 x 270 mm, 130 x 380 mm, 125 mm. For pouch sizes 190 x 330 mm, 250 x 400 mm, 300 x 450 mm, 250 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 – K231999 Steriking® LT-Blueline Pouches with Tyvek®	**Comparison**	**Primary Predicate Device** – K221377 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 STERRAD®	Different	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

	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 years post sterilization. The products are for single use only. The Steriking® LT-Blueline Pouches with Tyvek 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: For pouch sizes 90 x 200 mm, 90 x 250 mm, 130 x 270 mm, 130 x 380 mm, .094 lbs. For pouch sizes 190 x 330 mm, 250 x 400 mm, 300 x 450 mm, 1.194 pounds. NX Advanced Cycle: For pouch sizes 90 x 200 mm, 90 x 250 mm, 130 x 270 mm, 130 x 380 mm, .096 lbs. For pouch sizes 190 x 330 mm, 250 x 400 mm, 300 x 450 mm, 1.224 pounds. 100NX Duo Cycle: For pouch sizes 90 x 200 mm, 90 x 250 mm, 130 x 270 mm, 130 x 380 mm, .116 lbs. For pouch sizes 190 x 330 mm, 250 x 400 mm, 300 x 450 mm, 1.222 pounds. 100NX Flex Cycle: For pouch sizes 90 x 200 mm, 90 x 250 mm, 130 x 270 mm, 130 x 380 mm, .202 lbs. For pouch sizes 190 x 330 mm, 250 x 400 mm, 300 x 450 mm, 1.220 pounds. 100NX Standard Cycle: For pouch sizes 90 x 200 mm, 90 x 250 mm, 130 x 270 mm, 130 x		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 Pouches with Tyvek 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:

	380 mm, .202 lbs. For pouch sizes 190 x 330 mm, 250 x 400 mm, 300 x 450 mm, 4.478 pounds. Max Count of lumens: 1 lumen max for All cycles Max ID of lumens: NX Standard Cycle: 1 mm ID for all pouch sizes NX Advanced Cycle: 2 mm ID for all pouch sizes 100NX Cycle: 1 mm ID for all pouch sizes 100NX Flex Cycle: 1 mm ID for all pouch sizes 100NX Standard Cycle: 2 mm ID for all pouch sizes Max lumen lengths: NX Standard Cycle: For pouch sizes 90 x 200 mm, 90 x 250 mm, 130 x 270 mm, 130 x 380 mm, 125 mm. For pouch sizes 190 x 330 mm, 250 x 400 mm, 300 x 450 mm, 250 mm. NX Advanced Cycle: For pouch sizes 90 x 200 mm, 90 x 250 mm, 130 x 270 mm, 130 x 380 mm, 125 mm. For pouch sizes 190 x 330 mm, 250 x 400 mm, 300 x 450 mm, 250 mm. 100NX Duo Cycle: 850 mm for all pouch sizes 100NX Flex Cycle: 850 mm for all pouch sizes 100NX Standard Cycle: For pouch sizes 90 x 200 mm, 90 x 250 mm, 130 x 270 mm, 130 x 380 mm, 125 mm. For pouch sizes 190 x 330 mm, 250 x 400 mm, 300 x 450 mm, 250 mm.		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 Max 1 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

	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		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
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	H_2O_2 Sterilization Process as per: **STERRAD®** NX Standard NX Advanced 100NX Duo 100NX Flex 100NX Standard	No Change	H_2O_2 Sterilization Process as per: **STERRAD®** NX Standard NX Advanced 100NX Duo 100NX Flex 100NX Standard
Sterilant Validation	Achieved a 10^{-6} Sterility Assurance Level (SAL) of Geobacillus stearothermophilus. NX Standard NX Advanced 100NX Duo 100NX Flex 100NX Standard	No Change	Achieved a 10^{-6} Sterility Assurance Level (SAL) of Geobacillus stearothermophilus. NX Standard NX Advanced 100NX Duo 100NX Flex 100NX Standard
Package Integrity	Pass	No Change	Pass
Biocompatibility	Pass	No Change	Pass
Shelf-Life Pre-Sterilization	3 years	Different	5 years
Maintenance of Sterility	1 year	Different	3 years

<table>
<tr>
<td>Max weights</td>
<td>
<table>
<tr><th>Pouch size</th><th>NX Advanced Cycle</th><th>NX Standard Cycle</th><th>100NX Duo Cycle</th><th>100NX Flex Cycle</th><th>100NX Standard Cycle</th></tr>
<tr><td></td><td>(pounds)</td><td></td><td></td><td></td><td></td></tr>
<tr><td>300 x 450 mm</td><td>1.224</td><td>1.194</td><td>1.222</td><td>1.220</td><td>4.748</td></tr>
<tr><td>250 x 400 mm</td><td>1.224</td><td>1.194</td><td>1.222</td><td>1.220</td><td>4.748</td></tr>
<tr><td>190 x 330 mm</td><td>1.224</td><td>1.194</td><td>1.222</td><td>1.220</td><td>4.748</td></tr>
<tr><td>130 x 380 mm</td><td>0.096</td><td>0.094</td><td>0.116</td><td>0.202</td><td>0.202</td></tr>
<tr><td>130 x 270 mm</td><td>0.096</td><td>0.094</td><td>0.116</td><td>0.202</td><td>0.202</td></tr>
<tr><td>90 x 250 mm</td><td>0.096</td><td>0.094</td><td>0.116</td><td>0.202</td><td>0.202</td></tr>
<tr><td>90 x 200 mm</td><td>0.096</td><td>0.094</td><td>0.116</td><td>0.202</td><td>0.202</td></tr>
</table>
</td>
<td>Different</td>
<td>
<table>
<tr><th>Pouch size</th><th>NX Advanced Cycle</th><th>NX Standard Cycle</th><th>100NX Duo Cycle</th><th>100NX Flex Cycle</th><th>100NX Standard Cycle</th></tr>
<tr><td></td><td colspan="5">weight (pounds)</td></tr>
<tr><td>250 x 500 mm</td><td>1.393</td><td>1.382</td><td>1.400</td><td>1.400</td><td>4.476</td></tr>
<tr><td>250 x 390 mm</td><td>1.393</td><td>1.382</td><td>1.400</td><td>1.400</td><td>4.476</td></tr>
<tr><td>205 x 390 mm</td><td>1.393</td><td>1.382</td><td>1.400</td><td>1.400</td><td>4.476</td></tr>
<tr><td>160 x 600 mm</td><td>0.084</td><td>0.088</td><td>0.104</td><td>0.158</td><td>0.158</td></tr>
<tr><td>160 x 440 mm</td><td>0.084</td><td>0.088</td><td>0.104</td><td>0.158</td><td>0.158</td></tr>
<tr><td>150 x 300 mm</td><td>0.084</td><td>0.088</td><td>0.104</td><td>0.158</td><td>0.158</td></tr>
<tr><td>100 x 250 mm</td><td>0.084</td><td>0.088</td><td>0.104</td><td>0.158</td><td>0.158</td></tr>
<tr><td>75 x 200 mm</td><td>0.084</td><td>0.088</td><td>0.104</td><td>0.158</td><td>0.158</td></tr>
</table>
</td>
</tr>
<tr>
<td>Max Lumen Dimensions</td>
<td>Max Count of lumens:
1 lumen max for all pouch sizes

Max lumen Id:

NX Standard:
1 mm ID for all pouch sizes

NX Advanced:
2 mm ID for all pouch sizes

100NX Duo:
1 mm ID for all pouch sizes

100NX Flex:
1 mm ID for all pouch sizes

100NX Standard:
2 mm ID for all pouch sizes

Max lumen lengths:

NX Standard Cycle:
For pouch sizes 90 x 200 mm, 90 x 250 mm, 130 x 270 mm, 130 x 380 mm, 125 mm.

For pouch sizes 190 x 330 mm, 250 x 400 mm, 300 x 450 mm, 250 mm.

NX Advanced Cycle:
For pouch sizes 90 x 200 mm, 90 x 250 mm, 130 x 270 mm, 130 x 380 mm, 125 mm.

For pouch sizes 190 x 330 mm, 250 x 400 mm, 300 x 450 mm, 250 mm.

100NX Duo Cycle:
850 mm for all pouch sizes

100NX Flex Cycle:
850 mm for all pouch sizes</td>
<td>Different</td>
<td>1 mm min ID Lumen and Max 1 lumen for all cycles

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.

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.</td>
</tr>
</table>

	100NX Standard Cycle: For pouch sizes 90 x 200 mm, 90 x 250 mm, 130 x 270 mm, 130 x 380 mm, 125 mm. For pouch sizes 190 x 330 mm, 250 x 400 mm, 300 x 450 mm, 250 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	All self-seal pouches passed the 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**
100NX Standard	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**
100NX Standard	Biocompatibility	Cytotoxicity	Sterilized-Unaged	ISO 10993-5 ISO 10993-12 ISO 11607-1	14-530 2-245 2-289	Not greater than Grade 2 reactivity (mildly reactive)	No reduction of cell growth and cell lysis	**Pass**
100NX Standard	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**
100NX Standard	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**

NX Standard	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**
NX Advanced	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**
100NX Flex	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**
100NX Duo	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**
100NX Standard	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**
100NX Standard	Package Integrity, Post-Sterilization	Accelerated Aging	Sterilized and Aged (3 years accelerated aging)	ANSI/AAMI ST8:2013/(R)2018 AAMI TIR12:2010 ANSI/AAMI ST77:2017 ANSI/AAMI ST79:2017 ISO 11607-1 ASTM F1980	14-406 14-396 14-511 14-530 14-497	Seal maintains integrity	Pass No suspect seals were observed, and the test samples remained intact.	**Pass**
100NX Standard	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 K221377.

Discussion:

Any differences between the predicate's and the proposed device's performance testing has no impact on 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 K221377.