June 7, 2024

Wipak OY
% Amanda Singleton
Consultant
Compliance Systems International LLC
1083 Delaware Road
Buffalo, New York 14209

Re: K232625
Trade/Device Name: Steriking® Pouch for Robotic Instruments
Regulation Number: 21 CFR 880.6850
Regulation Name: Sterilization Wrap
Regulatory Class: Class II
Product Code: FRG
Dated: April 30, 2024
Received: May 1, 2024

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device"

(https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

Stephen A. Anisko -S

Digitally signed by Stephen A. Anisko -S
Date: 2024.06.07 16:22:04 -04'00'

for: Christopher K. Dugard, MS
Assistant Director
DHT4B: Division of Infection Control
and Plastic and Reconstructive Surgery Devices
OHT4: Office of Surgical and
Infection Control Devices

Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K232625

Device Name
Steriking® Pouch for Robotic Instruments

Indications for Use *(Describe)*

Steriking® Pouch for Robotic Instruments serve as an enclosure for Intuitive Endowrist Robotic Instruments during steam sterilization that maintains the sterility of the enclosed medical devices until they are used.

Pouches are intended for use as packaging material of Intuitive Endowrist Robotic Instruments for steam sterilization in health care establishments. The products are for single use only. The pouches allow sterilization, maintain sterility and enable aseptic presentation of packed medical device.

The recommended sterilization cycles are as follows:
Pre-vacuum steam at 132°C for 4 minutes; Drying time of 20 minutes
Pre-vacuum steam at 135°C for 3 minutes; Drying time of 16 minutes

The maximum load for the Steriking® Pouch for Robotic Instruments is a single Intuitive Endowrist Robotic Instrument or other medical devices with a combined weight of metal and plastics of 2.6 pounds or less.

Steriking® Pouch for Robotic Instruments consists of a paper backing (Bleached wood pulp, grammage 100 g/m2) with transparent plastic film laminate front (2 sheets of laminated plastic) with a total grammage of 55 g/m2, 1 sheet of oriented polyester 12 microns thick, 1 sheet of coextruded polypropylene 40 microns thick. The plastic laminate is triple heat sealed to the backing paper.

Steriking® Pouch for Robotic Instruments consists of pouch sizes that can be heat sealed, and pouch sizes that are self-sealed.

For heat-sealed sizes: The open end of the pouch is to be heat sealed once a device is inserted. Heat sealing parameters to provide a sterile barrier are 165°C-200°C (329°F - 392°F).

Steriking® Pouch for Robotic Instruments have Dimensional heat-seal configurations (2 sizes 200mm x 800mm, 250mm x 900mm).

Steriking® Pouch for Robotic Instruments with heat-seal maintains the sterility of the enclosed devices for up to 1 year post Steam sterilization and before sterilization has a maximum shelf life of 5 years from the date of manufacture.

For self-sealed sizes: The open end of the pouch is to be self sealed once a device is inserted. Self-sealable pouches are featured with adhesive strip allowing tight, impermeable closing of a pack. The closing flap is pre-folded to facilitate the closure. When closing the self-seal pouch the paper flap shall be folded along the pre-folded line. Flap should be pressed firmly against the laminate from the center working outwards to ensure a good, even seal.

Steriking® Pouch for Robotic Instruments have Dimensional self-seal configurations (2 sizes 200mm x 800mm, 250mm x 875mm).

Steriking® Pouch for Robotic Instruments with self-seal maintains the sterility of the enclosed devices for up to 1 year post Steam sterilization and before sterilization has a maximum shelf life of 3 years from the date of manufacture.

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."

K232625 510K Summary

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 Nastola Finland Contact: Amanda Singleton Phone: 716.440.7364 Date Prepared: 06/06/2024
Name of the device, including the trade or proprietary name if applicable, the common or usual name, and the classification name	Proprietary Name: Steriking® Pouch for Robotic Instruments Common Name: Peel Pouch Classification Name: Sterilization wrap Regulation number (21 CFR 880.6850) Product code (FRG)
Identification of the legally marketed device to which the submitter claims equivalence (Primary predicate device, reference predicate device)	Primary Predicate Device: K221016, Steriking® Packaging for Medical Devices Reference Device: K210810, Steriking® Packaging for Medical Devices
Description of the device	Steriking® Pouch for Robotic Instruments serve as an enclosure for Intuitive Endowrist Robotic Instruments during steam sterilization that maintains the sterility of the enclosed medical devices until used. Pouches are intended for use as packaging material of Intuitive Endowrist Robotic Instruments for steam sterilization in health care establishments. The products are for single use only. The sterilization pouches allow sterilization, maintain sterility and enable aseptic presentation of packed medical device. The Steriking® Pouch for Robotic Instruments consists of a paper backing (Bleached wood pulp, grammage 100g/m^2) with transparent plastic film laminate front (2 sheets of laminated plastic with a total grammage of 55 g/m^2, 1 sheet of oriented polyester 12 microns thick, 1 sheet of coextruded polypropylene 40 microns thick. The plastic laminate is triple heat sealed to the backing paper. Steriking® Pouch for Robotic Instruments consists of pouch sizes that can be heat sealed, and pouch sizes that are self-sealed.

Indications for use	Steriking® Pouch for Robotic Instruments serve as an enclosure for Intuitive Endowrist Robotic Instruments during steam sterilization that maintains the sterility of the enclosed medical devices until they are used. Pouches are intended for use as packaging material of Intuitive Endowrist Robotic Instruments for steam sterilization in health care establishments. The products are for single use only. The pouches allow sterilization, maintain sterility and enable aseptic presentation of packed medical device. The recommended sterilization cycles are as follows: Pre-vacuum steam at 132°C for 4 minutes; Drying time of 20 minutes Pre-vacuum steam at 135°C for 3 minutes; Drying time of 16 minutes The maximum load for the Steriking® Pouch for Robotic Instruments is a single Intuitive Endowrist Robotic Instrument or other medical devices with a combined weight of metal and plastics of 2.6 pounds or less. Steriking® Pouch for Robotic Instruments consists of a paper backing (Bleached wood pulp, grammage 100 g/m2) with transparent plastic film laminate front (2 sheets of laminated plastic) with a total grammage of 55 g/m2, 1 sheet of oriented polyester 12 microns thick, 1 sheet of coextruded polypropylene 40 microns thick. The plastic laminate is triple heat sealed to the backing paper. Steriking® Pouch for Robotic Instruments consists of pouch sizes that can be heat sealed, and pouch sizes that are self-sealed. For heat-sealed sizes: The open end of the pouch is to be heat sealed once a device is inserted. Heat sealing parameters to provide a sterile barrier are 165°C-200°C (329°F - 392°F). Steriking® Pouch for Robotic Instruments have Dimensional heat-seal configurations (2 sizes 200mm x 800mm, 250mm x 900mm). Steriking® Pouch for Robotic Instruments with heat-seal maintains the sterility of the enclosed devices for up to 1 year post Steam sterilization and before sterilization has a maximum shelf life of 5 years from the date of manufacture. For self-sealed sizes: The open end of the pouch is to be self sealed once a device is inserted. Self-sealable pouches are featured with adhesive strip allowing tight, impermeable closing of a pack. The closing flap is pre-folded to facilitate the closure. When closing the self-seal pouch the paper flap shall be folded along the pre-folded line. Flap should be pressed firmly against the laminate from the center working outwards to ensure a good, even seal. Steriking® Pouch for Robotic Instruments have Dimensional self-seal configurations (2 sizes 200mm x 800mm, 250mm x 875mm). Steriking® Pouch for Robotic Instruments with self-seal maintains the sterility of the enclosed devices for up to 1 year post Steam sterilization and before sterilization has a maximum shelf life of 3 years from the date of manufacture.

Technological Characteristics Comparison Table			
Comparison Element	**Submission Device K232625 Steriking® Pouch for Intuitive Endowrist Robotic Instruments**	**Comparison**	**Primary Predicate Device K221016 Steriking® Packaging for Medical Devices**
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
Intended Use	To serve as an enclosure for Intuitive Endowrist Robotic Instruments or medical devices during steam sterilization that maintains the sterility of the enclosed device until used.	Similar The difference is the added claim to sterilize 'Intuitive Endowrist Robotic Instruments'	To serve as an enclosure for medical devices during steam sterilization that maintains the sterility of the enclosed device until used.
Design	• Pouches • plastic film triple heat sealed to paper backing • thumb notches • chevron-type seal at end foropening • adhesive strip (self seal pouches only)	Same	• Pouches • plastic film triple heat sealed to paper backing • thumb notches • chevron-type seal at end for opening • adhesive strip
Principle of Operation	Intuitive Endowrist Robotic Instrument to be sterilized is put into pouch and the open parts of the pouches are closed by heat sealing or self-sealing. Sterilization packages then are subjected to validated sterilization operation of steam. Sterilant penetration is carried out through the medical grade paper into the package and microorganisms on the surface of the medical device are destroyed with the effect of the sterilant process. Other parameters of the sterilization process are temperature, pressure, humidity, time and are determined according to the sterilization type.	Similar The difference is the added claim to sterilize 'Intuitive Endowrist Robotic Instruments'	Medical device to be sterilized is put into pouch and the open parts of the pouches are closed by self-sealing. Sterilization packages then are subjected to validated sterilization operation of steam. Sterilant penetration is carried out through the medical grade paper into the package and microorganisms on the surface of the medical device are destroyed with the effect of the sterilant process. Other parameters of the sterilization process are temperature, pressure, humidity, time and are determined according to the sterilization type. After the sterilization is completed, the sterility of the enclosed medical device is maintained for 12 months.

Dimensions	200mm x 800mm 250 mm x 875 mm	Same	200mm x 800mm, 250mm x 875 mm
Backing Paper	Bleached wood pulp, grammage: 100g/m^2	Same	Bleached wood pulp, grammage: 100 g/m^2
Tensile Strength MD-kNm0	>66 N/15mm	Same	>66 N/15mm
Tensile Strength CD- kNm	>33 N/15mm	Same	>33 N/15mm
Tear Strength MD-mN	>550 Nm	Same	>550 Nm
Tear Strength CD-mN	>550 Nm	Same	>550 Nm
Burst Strength-kPa	>230 kpa	Same	>230 kpa
Porosity ISO 5636-3 ISO 5636-5	3.9 – 5.7 µm/Pa·s 24-34 s	Same	3.9 – 5.7 µm/Pa·s 24-34 s
Seal Strength – N/mm	Peel ≥ 1.5 N/15mm	Same	Peel ≥ 1.5 N/15mm
Transparent Film	Two sheets of laminated plastic with a total grammage of 55 g/m2. One sheet of oriented polyester 12 microns thick. One sheet of coextruded polypropylene 40 microns thick.	Same	Two sheets of laminated plastic with a total grammage of 55 g/m2. One sheet of oriented polyester 12 microns thick. One sheet of coextruded polypropylene 40 microns thick.
Sterilization Properties	Steam sterilization conditions are 4 minutes at 132° C or 3 minutes at 135° C	Same	Steam sterilization conditions are 4 minutes at 132° C or 3 minutes at 135° C
Sterilant Penetration	Full-cycle steam sterilization process will produce sufficient lethality to achieve a 12- log reduction, thus providing a 10^{-6}	Same	Full-cycle steam sterilization process will produce sufficient lethality to achieve a 12-log reduction, thus providing a 10^{-6} Sterility
	Sterility Assurance Level (SAL).		Assurance Level (SAL).
Material Compatibility	Compatible with Steam Sterilization	Same	Compatible with Steam Sterilization
Package Integrity Test	Closure integrity maintained before and after steam sterilization	Same	Closure integrity maintained before and after steam sterilization
Maintenance of Sterility – Shelf life post sterilization	1 year	Same	1 year
Shelf Life – Pre-sterilization	3 years	Same	3 years
Drying Time	20 minutes for 132° C/4 minutes condition 16 minutes for 135° C/3 minutes condition	Same	20 minutes for 132° C/4 minutes condition 16 minutes for 135° C/3 minutes condition
Microbial Barrier Properties	The paper of the sterile barrier system was examined on the packaging outer side for its germ proofness with air permeance after steam sterilization and is evaluated as “sufficiently germ-proof”	Same	The paper of the sterile barrier system was examined on the packaging outer side for its germ proofness with air permeance after steam sterilization and is evaluated as “sufficiently germ-proof”
Biocompatibility	Non-Cytotoxic	Same	Non-Cytotoxic

Technological Characteristics Comparison Table			
Comparison Element	**Submission Device K232625 Steriking® Pouch for Intuitive Endowrist Robotic Instruments**	**Comparison**	**Predicate Device K210810 Steriking® Packaging for Medical Devices**
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
Intended Use	To serve as an enclosure for Intuitive Endowrist Robotic Instruments or medical devices during steam sterilization that maintains the sterility of the enclosed device until used.	Similar The difference is the added claim to sterilize 'Intuitive Endowrist Robotic Instruments'	To serve as an enclosure for medical devices during steam sterilization that maintains the sterility of the enclosed device until used.
Design	• Pouches • plastic film triple heat sealed to paper backing • thumb notches • chevron-type seal at end for opening	Same	• Pouches • plastic film triple heat sealed to paper backing • thumb notches • chevron-type seal at end for opening

Principle of Operation	Intuitive Endowrist Robotic Instrument to be sterilized is put into pouch and the open parts of the pouches are closed by heat sealing or self-sealing. Sterilization packages then are subjected to validated sterilization operation of steam. Sterilant penetration is carried out through the medical grade paper into the package and microorganisms on the surface of the medical device are destroyed with the effect of the sterilant process. Other parameters of the sterilization process are temperature, pressure, humidity, time and are determined according to the sterilization type.	Similar The difference is the added claim to sterilize 'Intuitive Endowrist Robotic Instruments'	Medical device to be sterilized is put into pouch and the open parts of the pouches are closed by heat sealing. Sterilization packages then are subjected to validated sterilization operation of steam. Sterilant penetration is carried out through the medical grade paper into the package and microorganisms on the surface of the medical device are destroyed with the effect of the sterilant process. Other parameters of the sterilization process are temperature, pressure, humidity, time and are determined according to the sterilization type. Chemical process indicator is printed exterior on the pouch (printed on medical grade paper) changes color when exposed to sterilant vapor during processing. After the sterilization is completed, the sterility of the enclosed medical device is maintained for 12 months
Dimensions	200mm x 800mm, 250mm x 900 mm	Same	200mm x 800mm, 250mm x 900 mm
Backing Paper	Bleached wood pulp, grammage: 100g/m^2	Same	Bleached wood pulp, grammage: 100 g/m^2
Tensile Strength MD-kNm0	>66 N/15mm	Same	>66 N/15mm
Tensile Strength CD- kNm	>33 N/15mm	Same	>33 N/15mm
Tear Strength MD-mN	>550 Nm	Same	>550 Nm
Tear Strength CD-mN	>550 Nm	Same	>550 Nm
Burst Strength-kPa	>230 kpa	Same	>230 kpa
Porosity ISO 5636-3 ISO 5636-5	3.9 – 5.7 µm/Pa·s 24-34 s	Same	3.9 – 5.7 µm/Pa·s 24-34 s
Seal Strength – N/mm	Peel ≥ 1.5 N/15mm	Same	Peel ≥ 1.5 N/15mm
Transparent Film	Two sheets of laminated plastic with a total grammage of 55 g/m2. One sheet of oriented polyester 12 microns thick. One sheet of coextruded polypropylene 40 microns thick.	Same	Two sheets of laminated plastic with a total grammage of 55 g/m2. One sheet of oriented polyester 12 microns thick. One sheet of coextruded polypropylene 40 microns thick.
Sterilization Properties	Steam sterilization conditions are 4 minutes at 132° C or 3 minutes at 135° C	Same	Steam sterilization conditions are 4 minutes at 132° C or 3 minutes at 135° C

Sterilant Penetration	Full-cycle steam sterilization process will produce sufficient lethality to achieve a 12- log reduction, thus providing a 10^{-6} Sterility Assurance Level (SAL).	Same	Full-cycle steam sterilization process will produce sufficient lethality to achieve a 12-log reduction, thus providing a 10^{-6} Sterility Assurance Level (SAL).
Material Compatibility	Compatible with Steam Sterilization	Same	Compatible with Steam Sterilization
Package Integrity Test	Closure integrity maintained before and after steam sterilization	Same	Closure integrity maintained before and after steam sterilization
Maintenance of Sterility – Shelf life post sterilization	1 year	Same	1 year
Shelf Life – Pre-sterilization	5 years	Same	5 years
Drying Time	20 minutes for 132^{o} C/4 minutes condition 16 minutes for 135^{o} C/3 minutes condition	Same	20 minutes for 132^{o} C/4 minutes condition 16 minutes for 135^{o} C/3 minutes condition
Microbial Barrier Properties	The paper of the sterile barrier system was examined on the packaging outer side for its germ proofness with air permeance after steam sterilization and is evaluated as “sufficiently germ-proof”	Same	The paper of the sterile barrier system was examined on the packaging outer side for its germ proofness with air permeance after steam sterilization and is evaluated as “sufficiently germ-proof”
Biocompatibility	Non-Cytotoxic	Same	Non-Cytotoxic

Summary of Performance Tests:

Element	Standard reference	Acceptance Criteria	Results
Sterilant Penetration	AAMI TIR 12:2020, Designing, testing, and labeling medical devices intended for processing by health care facilities ISO 17665-1: 2006/2016 - Sterilization of health care products - Moist Heat- Part 1: Requirements for the development, validation, and routine control of a sterilization process for medical devices	Demonstrates that a minimum of 1.0x10^6 Geobacilus stearothermophilus spores were killed in a half-cycle (6-log reduction)	Pass
			Pass
Drying Time		Test samples do not exceed a 3% weight gain	Pass
Material Compatibility	EN 868-5: 2009 4.2.2.1, Annex B	no objections	Pass
	EN 868-5: 2009 4.2.2.1, Annex C	no pinholes	
	ASTM D 882:2012, procedure A	>= 20 N/15 mm	
	ISO 1924-3	> 66 N/15 mm	
		> 33 N/15 mm	
	Internal Method	152 µm +/- 10%	
	ISO 1974	> 550 N	
	DIN 53363	> 10 N	
	ISO 2758	> 230 kPa	
	ISO 5636-3	>=3.9 - 5.7 µm/Pa•s	
Puncture Resistance	ISO 14477 - Packaging. Flexible packaging material. Determination of puncture resistance.	Internal protocol, Accepted by Sponsor	Pass
Package Integrity	ASTM F1929 - Standard Test Method for Detecting Seal Leaks in Porous Medical Packaging by Dye Penetration	No leaks detected after dye migration	Pass
Microbial Barrier Properties	DIN EN ISO -11607-1:2017-10 Section 5.1.6. a) microbial barrier DIN 953-6, section 4.8.6. DIN 58953-6, section 3.8	Evaluated as "sufficiently germ-proof"	Pass

Shelf Life Prior to Sterilization	ASTM F1929-15 "Standard Test Method for Detecting Seal Leaks in Porous Medical Packaging by Dye Penetration	No leaks detected after dye migration	Pass
	EN 868-5 Packaging for terminally sterilized medical devices - Part 5: Sealable pouches and reels of porous materials and plastic film construction - Requirements and test methods	>= 1.5 N/15 mm	
	ISO 5636-3 Paper and board — Determination of air permeance	>=3.4 µm/Pa •s	
Shelf Life Post sterilization	ASTM F1980 − 16 Standard Guide for Accelerated Aging of Sterile Barrier Systems for Medical Devices	Executed as per standard, No Acceptance Criteria	Pass
	ASTM F1929-15 "Standard Test Method for Detecting Seal Leaks in Porous Medical Packaging by Dye Penetration	No leaks detected after dye migration	
	ASTM F88/F88M-15: Standard Test Method for Seal Strength of Flexible Barrier Materials	>= 1.5 N/15 mm	
Biocompatibility	ISO 10993-5, Biological evaluation of medical devices — Part 5: Tests for in vitro cytotoxicity	Not greater than Grade 2 reactivity (mildy reactive)	Pass
Evidence that printing ink on paper material does not leach into the interior of the pouch	DIN EN 646	5 Evaluation grades	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 legally marketed predicate device K221016.