January 23, 2022

Wipak OY
% Steven Singleton
Consultant
Compliance Systems International LLC.
7 Windham Hill
Mendon, New York 14056

Re: K210810
Trade/Device Name: Steiking Packaging for Medical Devices
Regulation Number: 21 CFR 880.6850
Regulation Name: Sterilization Wrap
Regulatory Class: Class II
Product Code: FRG
Dated: December 14, 2021
Received: December 23, 2021

Dear Steven 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,

For Clarence W. Murray, III, PhD
Assistant Director
DHT4B: Division of Infection Control
and Plastic 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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K210810

Device Name
Steriking Packaging for Medical Devices

Indications for Use *(Describe)*
Steriking Packaging for Medical Devices serve as an enclosure for medical devices during steam sterilization that maintains the sterility of the enclosed medical devices until use of the medical devices with a combined weight of metal and plastics of 2.6 pounds or less. The recommended sterilization cycles are as follows:
Pre-vacuum steam at 132oC for 4 minutes; Drying time of 20 minutes
Pre-vacuum steam at 135oC for 3 minutes; Drying time of 16 minutes

The Steriking Packaging for medical devices 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. 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 165oC-200oC (329oF-392oF).
Steriking Packaging for Medical Devices maintains the sterility of the enclosed devices for up to 12 months post Steam sterilization and before sterilization has a maximum shelf life of 5 years from the date of manufacture.
Steriking Packaging for Medical Devices Dimensional configurations (2 sizes 200mm x 800mm, 250mm x 900mm)

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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510k Summary
K210810

4. 510K Summary (in accordance with 21CFR807.92)

	510K Summary Elements per 21CFR807.92	**Summary**
a1	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 40 124 0290 Date Prepared: 02/03/21
a2	Name of the device, including the trade or proprietary name if applicable, the common or usual name, and the classification name	Proprietary Name: Steriking Packaging for Medical Devices Common Name: Peel Pouch Classification Name: Sterilization wrap, Peel Pouch
a3	Identification of the legally marketed device to which the submitter claims equivalence (predicate device)	K953776, Wipak Steriking Sterilization Pouches & Rolls
a4	Description of the device	The Steriking Packaging for Medical Devices 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. 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) Dimensional configurations as follows (2 sizes 200mm x 800mm, 250mm x 900mm).
a5	Indications for use	Steriking Packaging for Medical Devices serve as an enclosure for medical devices during steam sterilization that maintains the sterility of the enclosed medical devices until use of the medical devices with a combined weight of metal and plastics of 2.6 pounds or less. 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 Steriking Packaging for medical devices 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. 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 Packaging for Medical Devices maintains the sterility of the enclosed devices for up to 12 months post Steam sterilization and before sterilization has a maximum shelf life of 5 years from the date of manufacture. Steriking Packaging for Medical Devices Dimensional configurations (2 sizes 200mm x 800mm, 250mm x 900mm)
a6	technological characteristics compared to predicate (as follows)	See below as follows

b1. Comparison Element	**Submission Device – Steriking Packaging for Medical Devices**	Comparison	**Predicate Device – Wipak Steriking Peel Pouch, K953776**
Intended Use	To serve as an enclosure for medical devices during steam sterilization that maintains the sterility of the enclosed devices until used.	Same	To serve as an enclosure for medical devices during steam or gas sterilization that maintains 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	Similar	Pouches • plastic film triple heat sealed to paper backing • self-seal flap • thumb notches • chevron-type seal at end for opening
Principle of Operation	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. After the sterilization is completed, the sterility of the enclosed medical device is maintained for 12 months.	Same	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 60 months.
Dimensions	200mm x 800mm, 250mm x 875mm	Different	130 mm X 300 mm, 90 mm X 250 mm, 75mmX300mm
Backing Paper	Bleached wood pulp, grammage: 100g/m2	Similar	Bleached wood pulp, grammage: 70 g/m2
Tensile Strength MD-kNm	12.7	Similar	10
Tensile Strength CD-kNm	6.7	Similar	5.3
Tear Strength MD-mN	1000	Similar	750
Tear Strength CD-mN	1100	Similar	800
Burst Strength-kPa	690	Similar	550

Porosity - Bendtsen	425	Same	425
Seal Strength – N/mm	>6.09N/15mm	Similar	2,1 N/15 mm (Pouch up to 100mm wide) 2,5 N/15 mm (pouch greater than 100mm wide)
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 132º C or 3 minutes at 135º C	Different	Steam sterilization conditions are 3 minutes at 134º C or 15 minutes at 121º C
Sterilization Process Indicator	NA	Different	Steam Sterilization Process: blue indicators turn brown after steam sterilization. ISO 11140-1:2005 class 1:
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). Pouches heat sealable do not impede sterilant penetration to the double pouched contents.	Different	Not listed in 510K Summary
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	12 months	Different	Not listed in 510K Summary
Shelf Life – Pre-sterilization	5 years	Same	5 Years
Drying Time	20 minutes	Different	Not listed in 510K Summary
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”	Different	Not listed in 510K Summary
Biocompatibility	Non-Cytotoxic	Different	Not listed in 510K Summary

Summary of Non-Clinical Testing:

Provided below are a listing of performance testing that was used to evaluate the subject device to demonstrate that the device met the specification and the acceptance criteria of the standards and test methodology found in the table below.

Test Methodology	Purpose	Acceptance Criteria	Results
ISO 14477 - Packaging. Flexible packaging material. Determination of puncture resistance.	Punture Resistance	No pass/fail criteria	Acceptable =/> 13.1N
ASTM F1929-15 "Standard Test Method for Detecting Seal Leaks in Porous Medical Packaging by Dye Penetration 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 ISO 5636-3 Paper and board — Determination of air permeance	SHELF LIFE Prior to Sterilizaton	Seal Strength: =/>1.5N/15mm Seal Integrity: No dye leaks Air Permeability: =/>3.4um/Pa Peel Properties: free of of fibers after peeling	Pass
AAMI TIR 12:2010, Designing, Testing, and Labeling Reusable Medical Devices for Reprocessing in Health Care Facilities: A Guide for Medical Device Manufacturers	Sterilant Penetration & Drying Time	Biological indicator 6-log reduction in half cycle providing 10^{-6} SAL Drying time post sterilization moisture content weight gain <3%	Pass
DIN EN ISO -11607-1:2017-10 Section 5.1.6. a) microbisl barrier DIN 953-6, section 4.8.6. DIN 58953-6, section 3.8 and section 4.8.6.	Microbial Barrier Properties	Transmission of CFUs (Colony Forming Units) fron exterior of pouch to interior of pouch = 0	Pass
1. Tensile strength of film ASTM D882 2. Tensile strength of paper (MD) ISO 1924-3 3. Tensile trength of paper (CD) ISO 1924-3 4. Thickness 5. Tear resistance ISO 1974 6. Tear strength DIN 53363 7. Burst strength ISO 2758 8. Air permeance DIN 5636-5 9. Permeance after sterilization DIN 5636-5 10. Seal strength ASTM F88 11. Peel Characteristics EN 868-5:2009 12. Color fastness EIN DIN 646 13. No delamination or clouding 868-5:2009 14. Pinholes in film EN 868-5:2009	Material Compatibility	1. =/>20N/15mm 2. =/>66N/15mm 3. =/>33N/15mm 4. =152 +/- 10% µm 5. >550mN (MD & CD) 6. >10N 7. >230kPa 8. 3.9 – 5.7 µm/PAS 9. Corresponds 10. 1.5N/15mm 11. No irregularities or splitting >10mm 12. evaluation grade = 5 13. No objections 14. No pinholes	Pass
ISO 10993-5, Biological evaluation of medical devices — Part 5: Tests for in vitro cytotoxicity	Biocompatibility	If viability is reduced to <70% of the medium control then test item is considered to have cytotoxic potential	Pass 88% & 92% viability
ASTM F1980 − 16 Standard Guide for Accelerated Aging of Sterile Barrier Systems for Medical Devices	Shelf Life (post sterilization)	Dye Pentration: none Seal peel: =/>1.5N/15mm	Pass
ASTM F1929 - Standard Test Method for Detecting Seal Leaks in Porous Medical Packaging by Dye Penetration	Package Integrity	No dye penetration/channeling travelling full width of seal in ~5 seconds	Pass

Conclusion

The conclusions drawn from the non-clinical performance data demonstrate that the subject device is as safe, as effective and performs as well as or better than the legally marketed predicate device (K953776), Class II 21 CFR 880.6850, ProCode FRG.