May 5, 2022

Wipak OY
% Steven Singleton
Consultant
Compliance Systems International LLC
7 Windham Hill
Mendon, New York 14506

Re: K221016
Trade/Device Name: Steriking Packaging for Medical Devices
Regulation Number: 21 CFR 880.6850
Regulation Name: Sterilization Wrap
Regulatory Class: Class II
Product Code: FRG
Dated: March 31, 2022
Received: April 5, 2022

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

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

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)*
K221016

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 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 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 875mm)

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.

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 Contacts: Hanna Marttila, Phone: 358 (0)40 124 0290 Mr. Steven Singleton, Phone: 716 440 7364 Date Prepared: 2/18/2022
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 Regulation number (21 CFR 880.6850) Product code (FRG)
a3	Identification of the legally marketed device to which the submitter claims equivalence (predicate device)	K210810, Steriking Packaging for Medical Devices
a4	Description of the device	The Steriking Packaging for Medical Devices consists of a paper backing (Bleached wood pulp, grammage 100 g/m_2) 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 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 centre working outwards to ensure a good, even seal. Dimensional configurations as follows (2 sizes 200mm x 800mm, 250mm x 875mm).
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 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 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 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 875mm)
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 – Steriking Packaging for Medical Devices** K210810
Intended Use	To serve as an enclosure for medical devices during steam sterilization that maintains the sterility of the enclosed devices until used.	No Change	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 • Adhesive strip for self seal	Different	Pouches • plastic film triple heat sealed to paper backing • 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 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.	Different	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.
Dimensions	200mm x 800mm, 250mm x 875 mm	Different	200mm x 800mm, 250mm x 900 mm
Backing Paper	Bleached wood pulp, grammage: 100g/m2	No Change	Bleached wood pulp, grammage: 100 g/m2
Tensile Strength MD-kNm	>66 N/15mm	No Change	>66 N/15mm
Tensile Strength CD-kNm	>33 N/15mm	No Change	>33 N/15mm
Tear Strength MD-mN	>550 Nm	No Change	>550 Nm
Tear Strength CD-mN	>550 Nm	No Change	>550 Nm
Burst Strength-kPa	>230 kpa	No Change	>230 kpa

Porosity ISO 5636-3 ISO 5636-5	3.9 – 5.7 µm/Pa·s 24-34 s	No Change	3.9 – 5.7 µm/Pa·s 24-34 s
Seal Strength – N/mm	Peel ≥ 1.5 N/15mm	No Change	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.	No Change	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	No Change	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	No Change	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	No Change	Compatible with Steam Sterilization
Package Integrity Test	Closure integrity maintained before and after steam sterilization	No Change	Closure integrity maintained before and after steam sterilization
Maintenance of Sterility – Shelf life post sterilization	12 months	No Change	12 months
Shelf Life – Pre-sterilization	5 years	No Change	5 years
Drying Time	20 minutes	No Change	20 minutes
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”	No Change	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	No Change	Non-Cytotoxic