



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

September 7, 2023

Re: K231996

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 -
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by Eileen Cadel
-S
Date:
2023.09.07
13:46:02 -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

510(k) Number (if known)

K231996

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 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 1 year post sterilization. The products are for single use only.

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 max and 1 mm min ID x 1050 mm max length for all pouch sizes.

Lumen Cycle: 1 lumen max for all pouch sizes.

1 mm min ID for pouch sizes: 130 x 380 mm, 130 x 270 mm, 90 x 250 mm, 90 x 200 mm

2 mm min ID for pouch sizes: 300 x 450 mm, 250 x 400 mm, 190 x 330 mm

125 mm max length for pouch sizes: 130 x 380 mm, 130 x 270 mm, 90 x 250 mm, 90 x 200 mm

250 mm max length for pouch sizes: 300 x 450 mm, 250 x 400 mm, 190 x 330 mm

Max Weights:

1.234 pounds for pouch sizes below (Flexible, Lumen, and Non-Lumen Cycles)

300 x 450 mm

250 x 400 mm

190 x 330 mm

.122 pounds for pouch sizes below (Flexible and Lumen Cycles)

130 x 380 mm

130 x 270 mm

90 x 250 mm

90 x 200 mm

.204 pounds for pouch sizes below (Non-Lumen Cycle)

130 x 380 mm

130 x 270 mm

90 x 250 mm

90 x 200 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.

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"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."



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