January 3, 2019

Safe Secure Packing Co., Ltd.
Howard Jia, President
Yaoshan Industrial Park
Xiegang Town, Dongguan City, CN 523601

Re: K180139
Trade/Device Name: Safe Secure Sterilization Pouches and Rolls
Regulation Number: 21 CFR 880.6850
Regulation Name: Sterilization Wrap
Regulatory Class: Class II
Product Code: FRG
Dated: November 27, 2018
Received: November 28, 2018

Dear Howard Jia:

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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Elizabeth F. Claverie -S

For Tina Kiang, Ph.D.
Acting Director
Division of Anesthesiology,
General Hospital, Respiratory,
Infection Control, and Dental Devices
Office of Device Evaluation
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K180139

Device Name
Safe Secure Sterilization Pouches and Rolls

Indications for Use *(Describe)*
Safe Secure Sterilization Pouches and Rolls are intended to be used to enclose another medical device, in a single or double pouch configuration, that is to be sterilized by a health care provider using:
• Gravity steam at 121°C (250°F) for 30 minutes; 25 minutes dry time
• Pre-vacuum steam at 132°C (270°F) for 4 minutes; 20 minutes dry time
• Pre-vacuum steam at 134°C (273°F) for 3 minutes; 20 minutes dry time
• Pre-vacuum steam at 135°C (275°F) for 3 minutes; 16 minutes dry time
• Ethylene Oxide (EO) with a concentration of 735 mg/L at 55°C (131°F) and 50% to 80% relative humidity for 60 minutes. Aeration time of 8 hours at 60oC (140oF).
• The recommended hydrogen peroxide vapor sterilization cycle is the STERRAD® 100S Short Cycle.

The steam and EO device is not intended and has not been validated for sterilization of devices that contain lumens. The hydrogen peroxide device has been validated for devices that contain a lumen. The hydrogen peroxide device has been validated for devices that contain a lumen; the 100S has been validated for medical devices with a single stainless steel lumen with an inside diameter of ≥1mm and an length of ≤125mm as well as lumens with an inside diameter ≥2mm and a length of ≤250mm only.

The external chemical indicators on the pouches/rolls are intended to demonstrate that the device has been exposed to the steam. EO, or hydrogen peroxide sterilization process and to distinguish between processed and unprocessed devices. The chemical indicators change from green to purple after exposure to steam, from yellow to brown after exposure to ethylene oxide, and from blue to pink for hydrogen peroxide.

The Tyvek version of the pouch is for EO and hydrogen peroxide sterilization only.
If stored according to the recommended conditions, the products before sterilization have a maximum shelf life of 2 years from the date of manufacture. The pouches are intended to allow sterilization of the enclosed medical device(s) and also to maintain sterility (SAL=10-6). The subject device is intended and has been validated to maintain sterility of the enclosed devices for 6 months after steam sterilization, 24 months after EO sterilization (for paper pouch), two years after hydrogen peroxide sterilization and five years for EO sterilization (for Tyvek Pouch).
The maximum validated pouch load is 2.64 pounds (1.2kg).

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.

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The maximum validated pouch load is 2.64 pounds (1.2kg).

Pouch Material	Sterilization Method	Size	Model Number
Medical Grade Paper	Steam or EO Sterilization Pouch/Roll Products	L: 2 – 30” W: 2 – 30”	ABHSP1TAB ABSSP1TAB
Tyvek	EO Sterilization Pouch/Roll Products	W: 2 – 30”	ABSST1TAB ABHST1TAB
Tyvek	Hydrogen Peroxide Sterilization Pouch/Roll Products	L: 2 – 30” W: 2 – 30”	ABSST2TAB ABHST2TAB

K180139

510(k) Summary

Submission Sponsor

Safe Secure Packing (Shenzhen) Co., Ltd
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Date Prepared

November 27, 2018

Device Identification

Trade/Proprietary Name:	Safe Secure Sterilization Pouches and Rolls
Common/Usual Name:	Sterilization Pouch
Classification Name:	Sterilization Wrap
Classification Regulation:	21 CFR Part 880.6850
Product Code:	FRG
Device Class:	2
Classification Panel:	General and Plastic Surgery

Predicate Device

K153540 - Safe Secure Sterilization Pouch with Steam and Ethylene Oxide Process Indicators

Device Description

Tyvek Sterilization Pouches with Chevron Seal are constructed from an uncoated Tyvek backing of fine, continuous, high-density polyethylene fibers, with front material consisting of a clear, laminated polyethylene terephthalate / low density polyethylene (LDPE) or LDPE-ethylene- vinylacetate copolymer film.

The pouches are used to enclose medical devices that are to be sterilized by a healthcare provider following manufacturer's instructions, devices are inserted into Tyvek Sterilization Pouches and sealed.

The self-seal pouch permits sealing of the pouch without heat-sealing equipment, whereas the heat-sealable pouches must be heat sealed prior to the cycle.

Chemical Indicators, are placed on the outside of the sterilization pouches indicate sterilant exposure, and a way to differentiate pouches that have been processed in sterilization cycles from unprocessed units.

The color of the Indicators (3M™ Comply™ Hydrogen Peroxide Chemical Indicator 1248) changes from blue to pink after exposer to hydrogen peroxide sterilization. After completion of the sterilization process, the pouches maintain sterility of the enclosed medical devices for at least five years.

Indications for Use

Safe Secure Sterilization Pouches and Rolls are intended to be used to enclose another medical device, in a single or double pouch configuration, that is to be sterilized by a health care provider using:

- Gravity steam at 121°C (250°F) for 30 minutes; 25 minutes dry time
- Pre-vacuum steam at 132°C (270°F) for 4 minutes; 20 minutes dry time
- Pre-vacuum steam at 134°C (273°F) for 3 minutes; 20 minutes dry time
- Pre-vacuum steam at 135°C (275°F) for 3 minutes; 16 minutes dry time
- Ethylene Oxide (EO) with a concentration of 735 mg/L at 55°C (131°F) and 50% to 80% relative humidity for 60 minutes. Aeration time of 8 hours at 60oC (140°F).
- The recommended hydrogen peroxide vapor sterilization cycle is the STERRAD® 100S Short Cycle.

The steam and EO device is not intended and has not been validated for sterilization of devices that contain lumens. The hydrogen peroxide device has been validated for devices that contain a lumen; the 100S has been validated for medical devices with a single stainless steel lumen with an inside diameter of ≥1mm and an length of ≤125mm as well as lumens with an inside diameter ≥2mm and a length of ≤250mm only.

The external chemical indicators on the pouches/rolls are intended to demonstrate that the device has been exposed to the steam, EO, or hydrogen peroxide sterilization process and to distinguish between processed and unprocessed devices. The chemical indicators change from green to purple after exposure to steam, from yellow to brown after exposure to ethylene oxide, and from blue to pink for hydrogen peroxide.

The Tyvek version of the pouch is for EO and hydrogen peroxide sterilization only.

If stored according to the recommended conditions, the products before sterilization have a maximum shelf life of 2 years from the date of manufacture. The pouches are intended to allow sterilization of the enclosed medical device(s) and also to maintain sterility (SAL=10-6). The subject device is intended and has been validated to maintain sterility of the enclosed devices for 6 months after steam sterilization, 24 months after EO sterilization (for paper pouch), two years after hydrogen peroxide sterilization and five years for EO sterilization (for Tyvek Pouch).

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Tyvek	EO Sterilization Pouch/Roll Products	W: 2 – 30”	ABSST1TAB ABHST1TAB
Tyvek	Hydrogen Peroxide Sterilization Pouch/Roll Products	L: 2 – 30” W: 2 – 30”	ABSST2TAB ABHST2TAB

Technological Characteristics Comparison Table

The subject device has the same intended use of the device as its predicate and the same technological characteristics.

The primary difference is the addition of the STERRAD® 100S Short Cycle to the indications for use.

A hydrogen peroxide sterilization chemical indicator cleared under K170321 has been included for monitoring.

	Subject Device	**Predicate Device**	**Comparison of subject device with the predicate device**
Name of Company	Safe Secure	Safe Secure	Identical
Device Name	Sterilization Tyvek Sterilization Pouches	Sterilization Tyvek Sterilization Pouches	Identical
Intended use	The device is intended to be used to enclose another medical device, in a single or double pouch configuration, that is to be sterilized by a health care provider	The device is intended to be used to enclose another medical device, in a single or double pouch configuration, that is to be sterilized by a health care provider	Identical
Material Composition	Tyvek and PET/PE Film Medical Double Side Tape (for self-seal pouches only)	Tyvek and PET/PE Film Medical Double Side Tape (for self-seal pouches only)	Tyvek and PET/PE Film Medical Double Side Tape (for self-seal pouches only)
Hydrogen Peroxide Chemical Indicator Supplier	3M™ Comply™ Hydrogen Peroxide Chemical Indicator 1248 (K170321)	NA	NA
Biocompatibility	Materials and biological evaluations Cytotoxicity Test (ISO 10993-5) – Post Sterilization	Materials and biological evaluations – Post Sterilization: Cytotoxicity Test (ISO 10993-5) Pre-Sterilization: Cytotoxicity (ISO 10993-5), Maximization Sensitization (ISO 10993-10), Irritation/Intracutaneous Reactivity (ISO 10993-10)	Both were non-cytotoxic post sterilization.
Configuration	Single pouch configuration with chemical indicator	Single pouch configuration with chemical indicator	Identical
Configurations/ Dimensions	Various	Various	Same – both have various configurations

	Subject Device	Predicate Device	Comparison of subject device with the predicate device
Design	Adhesive laminated film is a clear, high strength material; Uncoated Tyvek is compatible with sterilization, resistant to microbial penetration, and resistant to puncture	Adhesive laminated film is a clear, high strength material; Uncoated Tyvek is compatible with sterilization, resistant to microbial penetration, and resistant to puncture	Identical
Device Construction	Self-seal and heat seal pouches: front and back materials are heat sealed together on three sides; fourth side (end) remains open for filling; end is sealed by heat (heat seal pouches) or by removing protective liner strip, folding along the pre-fold, and pressing to the film (self-seal pouches). Heat seal tubing: front and back materials are heat sealed together on two sides; two ends are open for selecting size and filling; ends are sealed by heat.	Self-seal and heat seal pouches: front and back materials are heat sealed together on three sides; fourth side (end) remains open for filling; end is sealed by heat (heat seal pouches) or by removing protective liner strip, folding along the pre-fold, and pressing to the film (self- seal pouches). Heat seal tubing: front and back materials are heat sealed together on two sides; two ends are open for selecting size and filling; ends are sealed by heat.	Identical
Materials	Clear laminated PET/LDPE or LDPE-EVA film (front) and uncoated HDPE Tyvek (back)	Clear laminated PET/LDPE or LDPE-EVA film (front) and uncoated HDPE Tyvek (back)	Identical
Package Integrity	Seal strength, microbial barrier, burst, and peel open characteristics meet ISO and ASTM requirements	Seal strength, microbial barrier, burst, and peel open characteristics meet ISO and ASTM requirements	Identical
Pouch Types	Self-seal pouch; Heat seal pouch; Heat seal tubing	Self-seal pouch; Heat seal pouch; Heat seal tubing	Identical
Shelf Life	2 years from date of manufacture for hydrogen peroxide chemical indicator	5 years for EO chemical indicator	The hydrogen peroxide CI has a two year shelf life.
Validated for use in Sterilization System	Validated to be used with hydrogen peroxide sterilization, EO and Steam Sterilization	Validated to be used with EO and Steam Sterilization	The new CI is validated to be used with hydrogen peroxide sterilization
Chemical Indicator	Hydrogen Peroxide CI attached to outside of pouch	EO or Steam CI attached to outside of pouch	The new CI is validated to be used with hydrogen peroxide sterilization

Summary of Non-Clinical Testing

This section includes a brief discussion of the nonclinical tests submitted, referenced, or relied on in the premarket notification submission to support a determination of substantial equivalence.

Test	Description		Results
Package Integrity	Seal Strength Test	ASTM F88/F88M-15	Pass
	Seal Leak Test	ASTM F1929-15	
	Sterilization Chemical Indicator Test and Visual Inspection	Visual examination	
Material Compatibility	Seal strength test, microbial barrier properties, burst test, and peel open test were studied to demonstrate material compatibility characteristics of the Tyvek Sterilization Pouches		Pass
Biocompatibility	Not direct patient-contacting devices; Materials are non-toxic. Biological evaluations meet acceptable criteria; Provides reasonable assurance for safety. Standards referenced include: ISO 10993-1 and ISO 10993-5.		Pass
Shelf Life	Physical properties and microbial barrier of the processed Tyvek Pouches was verified at the end of shelf life of 2 years		Pass

Test	Description	Results
Sterilization Validation	Full, half, and partial/fail cycles were used to validate the cycle. The following standards were used in the submission. Standards referenced include: ISO 11140-1, ISO 11138, ISO 14161	Pass
Chemical Indicator	Testing was performed to demonstrate compliance to Submissions for Chemical Indicators - Guidance for Industry and FDA Staff as applicable under K170321	Pass

Conclusion

The conclusions drawn from the nonclinical tests demonstrate that the device is as safe, as effective, and performs as well as or better than the legally marketed device cleared under K153540.