October 16, 2024

Shenzhen SafeSecure Medical Infection Control Tech Co., Ltd.
℅ Prithul Bom
Most Responsible Person
Regulatory Technology Services, LLC
1000 Westgate Drive,
Suite 510k
Saint Paul, Minnesota 55114

Re: K242839
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, JOJ
Dated: September 19, 2024
Received: September 19, 2024

Dear Prithul Bom:

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.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

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,

PAULO LARANJEIRA -S

Digitally signed by PAULO LARANJEIRA -S
Date: 2024.10.16 16:18:27 -04'00'

for: Christopher Dugard
Assistant Director
DHT4C: Division of Infection Control Devices
OHT4: Office of Surgical and Infection Control Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

Indications for Use

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

510(k) Number *(if known)*
K242839

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℃ (250℉) for 30 minutes; 25 minutes dry time
■ Pre-vacuum steam at 132℃ (270℉) for 4 minutes; 20 minutes dry time
■ Pre-vacuum steam at 134℃ (273℉) for 3 minutes; 20 minutes dry time
■ Pre-vacuum steam at 135℃ (275℉) for 3 minutes; 16 minutes dry time
■ Ethylene Oxide (EO) with a concentration of 735 mg/L at 55℃ (131℉) and 50% to 80% relative humidity for 60 minutes. Aeration time of 8 hours at 60℃ (140℉).
■ The recommended hydrogen peroxide vapor sterilization cycle is：
● Standard Cycle of STERRAD® 100S
● Standard cycle and Advanced cycle of STERRAD® NX
● Standard cycle, Flex cycle and Express cycle of STERRAD® 100NX
● Non Lumen Cycle, Lumen Cycle and Flexible Cycle of V-PRO® maX

The steam and EO device are 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 listed below:
■ Standard Cycle of STERRAD® 100S
- inside diameter ≥ 1 mm and length ≤ 125 mm
- inside diameter ≥ 2 mm and length ≤ 250 mm

■ Standard cycle of STERRAD® NX
● Single channel stainless steel lumens with:
- Inside diameter ≥ 1 mm and length ≤ 150 mm
- Inside diameter ≥ 2 mm and length ≤ 400 mm
● Single channel PE/PTFE tubing with:
- Inside diameter ≥ 1 mm and length ≤ 350 mm

■ Advanced cycle of STERRAD® NX
● Single channel stainless steel lumens with:
- Inside diameter ≥ 1 mm and length ≤ 500 mm

● Single PTFE lumen tubing with:
- Inside diameter ≥ 1 mm and length ≤ 1000 mm
● Single channel PE/PTFE flexible endoscopes with:
- Inside diameter ≥ 1 mm and length ≤ 850 mm

■ Standard cycle of STERRAD® 100NX
● Single channel stainless steel lumens with:
- Inside diameter ≥ 0.7 mm and length ≤ 500 mm
● Single channel PE/PTFE instruments with:

- Inside diameter ≥ 1 mm and length ≤ 1000 mm

■ Flex cycle of STERRAD® 100NX
● Single channel PE/PTFE flexible endoscope with:
- Inside diameter ≥ 1 mm and length ≤ 850 mm

■ Lumen Cycle of V-PRO® maX
△ Lumened and non-lumened instruments with diffusion-restricted spaces such as the hinged portion of forceps and scissors.
△ Medical devices, including single, dual and triple channeled rigid and semi-rigid endoscopes, with the following configurations:
● Single channeled devices with a stainless lumen that is ≥ 0.77mm internal diameter (ID) and ≤ 500mm in length
● Dual channeled devices with stainless steel lumens that are ≥ 0.77mm ID and ≤ 527mm in length
● Triple channeled devices with stainless steel lumens that are
- ≥1.2 mm ID and ≤ 275 mm in length
- ≥1.8 mm ID and ≤ 310 mm in length
or
- ≥2.8 mm ID and ≤ 317 mm in length

■ Flexible Cycle of V-PRO® maX
△ Two flexible endoscopes with a light cord (if not integral to the endoscope) and mat with no additional load. The flexible endoscopes may contain either:
● A single lumen that is ≥ 1 mm ID and ≤ 1050 mm in length
● Or two lumens with:
- One lumen that is ≥ 1 mm ID and ≤ 990 mm in length
- And the other lumen that is ≥ 1 mm ID and ≤ 850 mm in length
△ One flexible endoscope with a light cord (if not integral to endoscope) and mat and additional non-lumened instruments including instruments with diffusion-restricted areas such as the hinged portion of forceps or scissors. The flexible endoscopes my contain either:
● A single lumen that is ≥ 1 mm ID and ≤ 1050 mm in length

● Or two lumens with:
- One lumen that is ≥ 1 mm ID and ≤ 990 mm in length
- And the other lumen that is ≥ 1 mm ID and ≤ 850 mm in length

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 or from Pink to Cocoa after exposure to steam, from yellow to brown or from Blue to Brown after exposure to ethylene oxide, and from blue to pink for hydrogen peroxide.

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

If stored according to the recommended conditions, the products before sterilization have a maximum shelf life of 5 years(for paper pouch) and 2 years(for Tyvek pouch) 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 12 months after steam sterilization and 24 months after EO sterilization(for paper pouch), and, 2 years after hydrogen peroxide sterilization (for Tyvek Pouch).

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"	ABSSP ABHSP ABHRP
Tyvek	Hydrogen Peroxide Sterilization Pouch/Roll Products	L: 2" – 30" W: 2" – 30"	ABSST ABHST ABHRT

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."

K242839 – 510(k) Summary

Submission Sponsor

Shenzhen SafeSecure Medical Infection Control Tech Co., Ltd.
6A01, Block 1, Ahoke Plaza, DaLing Community, Minzhi Street, Longhua District,
ShenZhen City, Guangdong Province
518109 China.

Parker Lee
Tel: 86-755-27040468
Fax: 86-755-27040488
tse@anbaopack.com

Date Prepared

October 10, 2024

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
Subsequent Product Code	JOJ
Device Class:	Class II
Classification Panel:	General Hospital

Predicate Device

K180139 - Safe Secure Sterilization Pouches and Rolls

Device Description

The device is made from porous material printed chemical indicator thermally sealed to a plastic film, additionally Self-Seal has medical double side tape.

They are divided according to porous material to paper pouch and Tyvek pouch. Paper Pouch are constructed from uncoated medical paper and plastic film; it can be used with steam and EO sterilization. Tyvek Pouch are constructed from an uncoated Tyvek and plastic film, , it can be used with hydrogen peroxide sterilization.

The device is preformed sterile barrier systems, sealed 2 sides (roll for left and right) or 3 sides(pouch for left, right and top). The remaining edges can be Heat-Sealed or Self-Sealed to form a sealing system. 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.

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

The devices contain chemical process indicator intended to demonstrate that the device has been exposed to the steam, EO and vapor hydrogen peroxide Sterilization.

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℃ (250℉) for 30 minutes; 25 minutes dry time
- Pre-vacuum steam at 132℃ (270℉) for 4 minutes; 20 minutes dry time
- Pre-vacuum steam at 134℃ (273℉) for 3 minutes; 20 minutes dry time
- Pre-vacuum steam at 135℃ (275℉) for 3 minutes; 16 minutes dry time
- Ethylene Oxide (EO) with a concentration of 735 mg/L at 55℃ (131℉) and 50% to 80% relative humidity for 60 minutes. Aeration time of 8 hours at 60℃ (140℉).
- The recommended hydrogen peroxide vapor sterilization cycle is：
  - Standard Cycle of STERRAD® 100S
  - Standard cycle and Advanced cycle of STERRAD® NX
  - Standard cycle, Flex cycle and Express cycle of STERRAD® 100NX
  - Non Lumen Cycle, Lumen Cycle and Flexible Cycle of V-PRO® maX

The steam and EO device are 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 listed below:

- Standard Cycle of STERRAD® 100S
  - inside diameter ≥ 1 mm and length ≤ 125 mm
  - inside diameter ≥ 2 mm and length ≤ 250 mm

- Standard cycle of STERRAD® NX
  - Single channel stainless steel lumens with:
    - Inside diameter ≥ 1 mm and length ≤ 150 mm
    - Inside diameter ≥ 2 mm and length ≤ 400 mm
  - Single channel PE/PTFE tubing with:
    - Inside diameter ≥ 1 mm and length ≤ 350 mm

- Advanced cycle of STERRAD® NX
  - Single channel stainless steel lumens with:
    - Inside diameter ≥ 1 mm and length ≤ 500 mm

- Single PTFE lumen tubing with:
  - Inside diameter ≥ 1 mm and length ≤ 1000 mm
- Single channel PE/PTFE flexible endoscopes with:
  - Inside diameter ≥ 1 mm and length ≤ 850 mm

■ Standard cycle of STERRAD® 100NX
- Single channel stainless steel lumens with:
  - Inside diameter ≥ 0.7 mm and length ≤ 500 mm
- Single channel PE/PTFE instruments with:
  - Inside diameter ≥ 1 mm and length ≤ 1000 mm

■ Flex cycle of STERRAD® 100NX
- Single channel PE/PTFE flexible endoscope with:
  - Inside diameter ≥ 1 mm and length ≤ 850 mm

■ Lumen Cycle of V-PRO® maX

△ Lumened and non-lumened instruments with diffusion-restricted spaces such as the hinged portion of forceps and scissors.

△ Medical devices, including single, dual and triple channeled rigid and semi-rigid endoscopes, with the following configurations:
- Single channeled devices with a stainless lumen that is ≥ 0.77mm internal diameter (ID) and ≤ 500mm in length
- Dual channeled devices with stainless steel lumens that are ≥ 0.77mm ID and ≤ 527mm in length
- Triple channeled devices with stainless steel lumens that are
  - ≥1.2 mm ID and ≤ 275 mm in length
  - ≥1.8 mm ID and ≤ 310 mm in length

    or
  - ≥2.8 mm ID and ≤ 317 mm in length

■ Flexible Cycle of V-PRO® maX

△ Two flexible endoscopes with a light cord (if not integral to the endoscope) and mat with no additional load. The flexible endoscopes may contain either:
- A single lumen that is ≥ 1 mm ID and ≤ 1050 mm in length
- Or two lumens with:
  - One lumen that is ≥ 1 mm ID and ≤ 990 mm in length
  - And the other lumen that is ≥ 1 mm ID and ≤ 850 mm in length

△ One flexible endoscope with a light cord (if not integral to endoscope) and mat and additional non-lumened instruments including instruments with diffusion-restricted areas such as the hinged portion of forceps or scissors. The flexible endoscopes my contain either:
- A single lumen that is ≥ 1 mm ID and ≤ 1050 mm in length
- Or two lumens with:

- One lumen that is ≥ 1 mm ID and ≤ 990 mm in length
- And the other lumen that is ≥ 1 mm ID and ≤ 850 mm in length

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 or from Pink to Cocoa after exposure to steam, from yellow to brown or from Blue to Brown after exposure to ethylene oxide, and from blue to pink for hydrogen peroxide.

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

If stored according to the recommended conditions, the products before sterilization have a maximum shelf life of 5 years(for paper pouch) and 2 years(for Tyvek pouch) 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 12 months after steam sterilization and 24 months after EO sterilization(for paper pouch), and, 2 years after hydrogen peroxide sterilization (for Tyvek Pouch).

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"	ABSSP ABHSP ABHRP
Tyvek	Hydrogen Peroxide Sterilization Pouch/Roll Products	L: 2" – 30" W: 2" – 30"	ABSST ABHST ABHRT

Predicate Technology Comparison

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

a) extend the expiry date of Paper pouch to 12 months after steam sterilization,
b) add the indicator printed in Paper pouch intended to demonstrate that the device has been exposed to the steam and EO,
c) add application of Tyvek pouch with Standard cycle and Advanced cycle of STERRAD® NX, Standard cycle, Flex cycle and Express cycle of

STERRAD® 100NX, Non Lumen Cycle, Lumen Cycle and Flexible Cycle of V-PRO® maX, and,

d) add parameters of rotary sealer

Table 1: Primary Predicate Device Technological Comparison

	Subject Device	Predicate Device	Comparison
510(k) Number	**K242839**	**K180139**	
Product name	Safe Secure Sterilization Pouches and Rolls	Safe Secure Sterilization Pouches and Rolls	Identical
Manufacturer	Shenzhen SafeSecure Medical Infection Control Tech Co., Ltd.	Shenzhen SafeSecure Medical Infection Control Tech Co., Ltd.	Identical
Classification	II	II	Identical
Product Code	FRG	FRG	Identical
Regulation Number	21 CFR 880.6850	21 CFR 880.6850	Identical
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 60°C (140°F). ■ The recommended hydrogen peroxide vapor sterilization cycle is: ● Standard Cycle of STERRAD® 100S ● Standard cycle and Advanced cycle of STERRAD® NX ● Standard cycle, Flex cycle and Express cycle of STERRAD® 100NX ● Non Lumen Cycle, Lumen Cycle and Flexible Cycle of V-PRO® maX	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 60°C (140°F). • The recommended hydrogen peroxide vapor sterilization cycle is the STERRAD® 100S Standard Cycle.	Similar[1]

	Subject Device	Predicate Device	Comparison
510(k) Number	**K242839**	**K180139**	
Configuration	Pouch or Roll	Pouch or Roll	Identical
Design	Adhesive laminated film is a clear, high strength material; Uncoated Porous material is compatible with sterilization, resistant to microbial penetration, and resistant to puncture	Adhesive laminated film is a clear, high strength material; Uncoated Porous material is compatible with sterilization, resistant to microbial penetration, and resistant to puncture	Identical
Primary Material	Medical paper & PET/CPP Film or Tyvek & PET/SPE Film, Medical Double Side Tape (for Self-Seal pouches only)	Medical paper & PET/CPP Film or Tyvek & PET/SPE Film, Medical Double Side Tape (for Self-Seal pouches only)	Identical
Chemical Indicator	Steam: green to purple or pink to cocoa EO: yellow to brown or blue to brown H_2O_2: blue to pink	Steam: green to purple EO: yellow to brown H_2O_2: blue to pink	Similar[2]
Seal Strength Pre-Sterilization, ASTM F88/F88M	⩾ 2.0N/15mm	⩾ 2.0N/15mm	Identical
Seal strength Post sterilization, ASTM F88/F88M	Steam: ⩾ 1.5N/15mm EO: ⩾ 1.2N/15mm H2O2: ⩾ 2.0N/15mm	Steam: ⩾ 1.5N/15mm EO: ⩾ 1.2N/15mm H2O2: ⩾ 2.0N/15mm	Identical
Seal Integrity Post sterilization	Visually examine the seal area through the transparent side of the package. No Channels with Dye penetration.	Visually examine the seal area through the transparent side of the package. No Channels with Dye penetration.	Identical
Peeling open	Peeling open and visual. No broken paper or film.	Peeling open and visual. No broken paper or film.	Identical
Shelf Life	Paper Pouch：5 years before Sterilization, and Tyvek Pouch: 2 years before Sterilization	Paper Pouch：5 years before Sterilization Tyvek Pouch: 2 years before Sterilization	Identical

	Subject Device	Predicate Device	Comparison
510(k) Number	**K242839**	**K180139**	
Maintenance of package integrity	Paper Pouch：12 months after steam sterilization and 24 months after EO sterilization Tyvek Pouch: 24 months after hydrogen peroxide	Paper Pouch：6 months after steam sterilization and 2 years after EO sterilization Tyvek Pouch: 24 months after hydrogen peroxide sterilization.	Identical

[1] The testing reports demonstrate the safety and effectiveness of device for their Indications for Use.
[2] The testing reports demonstrate the safety and effectiveness of device for their Chemical Indicator.

Summary of Non-Clinical Testing

The predicate and subject devices (pre-formed pouch and roll) in their pre-sterilized final finished form are identical in formulation, processing, and geometry, and no other chemicals have been added (e.g., plasticizers, fillers, additives, cleaning agents, mold release agents), with the exception of the steam and EO sterilization chemical process indicator on the exterior of the device.

This section includes a brief discussion of the nonclinical tests submitted, referenced, or relied on in the premarket notification submission to support subject device performance.

Test	Standard or test method	Acceptance Criteria	Result
Seal Width	Ruler	More than 8mm	Pass
Seal Strength	ASTM F88/F88M	Pre sterilization: ≥ 2N/15mm Post sterilization: Steam: ≥ 1.5N/15mm EO: ≥ 1.2N/15mm H2O2: ≥ 2.0N/15mm	Pass
Dye penetration	ASTM F1929	No Channels with Dye penetration.	Pass
Peeling open	Peeling open and visual	No broken paper or film	Pass
Chemical indicator color	ISO 11140-1	Meets the requirements of Guidance for Industry and FDA Staff	Pass
Sterilant Penetration	ISO 11138-1, ISO 11737-2, ISO 22441 Half cycles were used to validate the cycle.	The positive control group had bacterial growth, the negative control group had no growth, and the experimental group had no growth.	Pass

Maintenance of package integrity	Expiry date Validation Test; Conducted the expiry date testing as real time aging method. Paper Pouch: after Steam sterilization: 12 months. after EO sterilization: 24 months. Tyvek Pouch: after hydrogen peroxide sterilization: 24 months.	The device performance shall be meet the requirements of maintenance of package integrity.	Pass
Shelf Life	Shelf Life Validation Test; Conducted the shelf life testing as real time aging method. Paper Pouch:5 years before Sterilization Tyvek Pouch: 2 years before Sterilization	The device performance shall be meet the requirements of shelf life.	Pass
Biocompatibility	ISO 10993-5	Non-cytotoxic.	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 K180139.