February 21, 2025

Shanghai Jianzhong Medical Packaging Co., Ltd.
Xinhua Wei
Medical Device Regulatory Affairs Specialist
Bldg 16, 789# Puxing Road, Minhang District
Shanghai, 201114
China

Re: K242898
Trade/Device Name: Sterilization Pouches and Reels
Regulation Number: 21 CFR 880.6850
Regulation Name: Sterilization Wrap
Regulatory Class: Class II
Product Code: FRG, JOJ
Dated: September 24, 2024
Received: January 24, 2025

Dear Xinhua Wei:

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,

Stephen A. Anisko -S

Digitally signed by Stephen A. Anisko -S
Date: 2025.02.21 15:53:10 -05'00'

for: Christopher K. Dugard, M.S.
Division 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)*
K242898

Device Name
Sterilization Pouches and Reels

Indications for Use *(Describe)*
The Sterilization Pouches and Reels is intended to provide health care workers with an effective method to enclosed devices in a single or double pouch configuration by steam or ethylene oxide sterilization. The recommended sterilization cycle parameters are as follows:

a) Steam sterilization at 132°C (270°F) for 4 minutes; Drying time of 20 minutes.
b) Ethylene Oxide (EO) with a concentration of 800 mg/L at 55 °C (131 °F) and 40%-80% relative humidity for 6 hours. Aeration time of 7 days at 20°C (68 °F).

The Sterilization Pouches and Reels is composed of medical grade paper and medical compound film, maintains the sterility of the enclosed devices for up to 12 months post Steam or EO gas sterilization, and before sterilization has a maximum shelf life of 5 years from the date of manufacture. The pouch's external chemical indicators are designed to indicate to the user that the pouch has undergone either a steam or EO Sterilization process. Sterilization indicators will change color according to the sterilization method (Steam, Ethylene oxide). The color of steam sterilization indicator changes from Pink before sterilization to Cocoa after sterilization. The color of Ethylene oxide sterilization indicator changes from Blue before sterilization to Golden Brown after sterilization. The maximum validated pouch load is 1.87 lbs. (850g); The maximum validated reel load is 1.87 lbs. (850 g)

The following tables (Table 1~5) identifies the size of subject device and its Maximum validated load.
Table 1:Sterilization Pouches, self seal

Size of device		Content/Max Load (lbs.)		
Inch	Metric	Metal	Plastic	Gauze/Linens
2.25″×4″	57× (100+30) mm	0.004	0.0088	0.005
2.25″×2.75″	57× (70+30) mm	0.004	0.0088	0.004
2.75″×9″	70× (230+30) mm	0.020	0.04	0.02
3.5″×6.5″	90× (135+30) mm	0.016	0.032	0.016
3.5″×9″	90× (230+30) mm	0.024	0.12	0.024
3.5″×10.5″	90× (270+30) mm	0.032	0.15	0.032
3.5″×22″	90× (560+30) mm	0.072	0.32	0.072
5″×15″	127× (380+30) mm	0.062	0.30	0.062
5.25″×10″	135× (254+29) mm	0.045	0.22	0.045
5.25″×10″	135× (255+30) mm	0.045	0.22	0.045
5.25″×12″	135× (305+30) mm	0.052	0.26	0.05
5.25″×13″	140× (330+30) mm	0.072	0.36	0.07
6″×9″	150× (230+30) mm	0.055	0.27	0.05
7.5″×13″	190× (330+30) mm	0.102	0.48	0.10
8″×12.5″	200× (320+30) mm	0.12	0.53	0.10
10″×14.5″	250× (370+30) mm	0.21	0.65	0.19
10.6″×17″	270× (400+30) mm	0.38	0.78	0.22
10.5″×17″	270× (430+30) mm	0.42	0.82	0.24
12″×15″	300× (380+30) mm	0.52	0.90	0.23
12″×16.5″	300× (420+30) mm	0.58	1.02	0.25
12″×18″	300× (460+30) mm	0.68	1.10	0.28
14″×19″	355× (480+30) mm	0.92	1.10	0.34

15″×25″	380× (635+30) mm	1.30	1.10	0.50
20″×22″	500× (560+40) mm	1.87	1.10	0.60

Table 2 Sterilization Pouches, flat, heat seal

Size of device		Content/Max Load (Ibs.)		
Inch	Metric	Metal	Plastic	Gauze/Linens
3.5″×22″	90×560mm	0.005	0.01	0.020
4″×12″	100×300mm	0.004	0.0088	0.0176
5″×15″	127×380mm	0.07	0.20	0.055
6″×10″	150×254mm	0.06	0.19	0.05
6″×22″	150×560mm	0.12	0.32	0.10
7.5″×13″	190×330mm	0.10	0.25	0.09
8″×20″	200×500mm	0.12	0.53	0.10
12″×15″	300×380mm	0.44	0.54	0.38
12″×18″	300×460mm	0.58	0.74	0.52
16.5″×22.5″	420×570mm	1.87	1.10	0.60

Table 3 Sterilization Pouches, gusseted, heat seal

Size of device		Content/Max Load (Ibs.)		
Inch	Metric	Metal	Plastic	Gauze/Linens
4″×12″	100×50×300mm	0.004	0.0088	0.0176
4″×14″	100×50×360mm	0.02	0.04	0.025
6″×16″	150×50×400mm	0.05	0.12	0.04
6″×18″	150×50×460mm	0.06	0.18	0.06
8″×20″	200×55×500mm	0.12	0.53	0.10
8″×16″	200×55×400mm	0.12	0.48	0.10
8″×19″	250×65×480mm	0.30	0.74	0.26
12″×22″	300×80×550mm	1.15	0.98	0.40
16.5″×22.5″	420×100×570mm	1.87	1.10	0.60

Table 4 Sterilization Reels, flat, heat seal

Size of device		Content/Max Load (Ibs.)		
Inch	Metric	Metal	Plastic	Gauze/Linens
3″	75mm×30.5m	0.02	0.04	0.02
4″	100mm×30.5m	0.025	0.15	0.032
6″	150mm×30.5m	0.06	0.27	0.07
8″	200mm×30.5m	0.10	0.53	0.10
10″	250mm×30.5m	0.12	0.53	0.10
2″	50mm × 200m	0.004	0.0088	0.004
2.15″	55mm × 200m	0.004	0.0088	0.005
3″	75mm × 200m	0.02	0.04	0.002
4″	100mm × 200m	0.025	0.08	0.035
4.7″	120mm × 200m	0.04	0.10	0.04
6″	150mm × 200m	0.06	0.20	0.06
8″	200mm × 200m	0.12	0.38	0.08
10″	250mm×200m	0.12	0.53	0.10
12″	300mm × 200m	0.52	0.53	0.25
14″	350mm × 200m	0.92	1.05	0.34
16″	400mm × 200m	1.08	1.07	0.52
18″	450mm × 200m	1.30	1.10	0.58
20″	500mm × 200m	1.87	1.10	0.60

Table 5 Sterilization Reels, gusseted, heat seal

Size of device		Content/Max Load (lbs.)		
Inch	Metric	Metal	Plastic	Gauze/Linens
4.15″	55mm × 100m	0.004	0.0088	0.004
3″	75mm × 100m	0.02	0.04	0.04
4″	100mm × 100m	0.05	0.15	0.08
6″	150mm × 100m	0.07	0.20	0.10
8″	200mm × 100m	0.12	0.53	0.10
10″	250mm × 100m	0.12	0.53	0.10
12″	300mm × 100m	1.15	0.98	0.40
14″	350mm × 100m	1.35	1.0	0.50
16″	400mm × 100m	1.65	1.03	0.58
18″	450mm × 100m	1.87	1.10	0.60
20″	500mm × 100m	1.87	1.10	0.60

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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510(k) Summary

This 510(k) Summary is being submitted in accordance with requirements of Title 21, CFR Section 807.92.The

assigned 510(k) Number: K242898

1. Date of Preparation: February 20, 2025

2. Sponsor Identification

Shanghai Jianzhong Medical Packaging Co., Ltd.

Bldg 16, 789# Puxing Road, Minhang District, Shanghai 201114, P.R. China

Registration Number: 3005030944.

Contact Person: Xinhua Wei

Position: Medical Device Regulatory Affairs Specialist

Tel: +86-21-54315666-5201

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Email: weixinhua@mpackchina.com

3. Identification of Proposed Device

Trade Name: Sterilization Pouches and Reels

Common Name: Sterilization Pouches and Reels

Regulatory Information

Classification Name: Wrap, Sterilization

Classification: II;

Product Code: FRG;

Subsequent Product Code: JOJ;

Regulation Number: 21 CFR 880.6850

Review Panel: General Hospital;

4. Identification of Predicate Device

510(k) Number: K221875

Product Name: Sterilization Pouch and Roll

Regulation Number: 21 CFR 880.6850

Regulation Name: Sterilization Wrap

Regulatory Class: II

Product Code: FRG,

Subsequent Product Code: JOJ

Dated: January 17, 2023

Received: January 17, 2023

5. Device Description

The Sterilization Pouches and Reels is composed of medical grade paper and medical compound film. It is intended to be used to contain medical devices to be terminally sterilized by Steam or EO sterilization process. The recommended sterilization cycle parameters are as follows:

a) Steam sterilization at 132°C (270°F) for 4 minutes; Drying time of 20 minutes.

b) Ethylene Oxide (EO) with a concentration of 800 mg/L at 55 °C (131 °F) and 40%-80% relative humidity for 6 hours. Aeration time of 7 days at 20°C (68 °F).

The medical devices are inserted into the Pouches/Reels, sealed, and then sterilized for the EO or Steam Sterilization Process. The heat-sealed Pouches/Reels are heat sealed prior to sterilization processing. After completion of the sterilization process, the Pouches/Reels maintain sterility of the enclosed medical devices until the seal is opened. The Sterilization Pouches and Reels maintains the sterility of the enclosed devices for up to 12 months post Steam or EO gas sterilization, and before sterilization has a maximum shelf life of 5 years from the date of manufacture.

The Sterilization Pouches and Reels is printed with chemical indicator bars that changed from Pink to Cocoa(Steam) or Blue to Golden Brown (EO) when exposed to steam vapor or EO gas during process. The steam and EO chemical indicator offer an addition way to verify processing in the sterilization cycle. The chemical indicator should be used in addition to, not in place of, the biological indicator. The steam and EO chemical indicators do not signify sterilization; they only indicate that the indicators have been exposed to the Steam or EO.

6. Indication for Use Statement

The Sterilization Pouches and Reels is intended to provide health care workers with an effective method to enclosed devices in a single or double pouch configuration by steam or ethylene oxide sterilization. The recommended sterilization cycle parameters are as follows:

a) Steam sterilization at 132°C (270°F) for 4 minutes; Drying time of 20 minutes.

b) Ethylene Oxide (EO) with a concentration of 800 mg/L at 55 °C (131 °F) and 40%-80% relative humidity for 6 hours. Aeration time of 7 days at 20°C (68 °F).

The Sterilization Pouches and Reels is composed of medical grade paper and medical compound film, maintains the sterility of the enclosed devices for up to 12 months post Steam or EO gas sterilization, and before sterilization has a maximum shelf life of 5 years from the date of manufacture. The pouch's external chemical indicators are designed to indicate to the user that the pouch has undergone either a steam or EO Sterilization process. Sterilization indicators will change color according to the sterilization method (Steam, Ethylene oxide). The color of steam sterilization indicator changes from Pink before sterilization to Cocoa after sterilization. The color of

Ethylene oxide sterilization indicator changes from Blue before sterilization to Golden Brown after sterilization.

The maximum validated pouch load is 1.87 lbs. (850g); The maximum validated reel load is 1.87 lbs. (850 g)

(Model and Dimension and Content/Max. Load)

Item	Size of Device		Content/Max Load(Ibs)		
	Inch	Metric	Metal	Plastic	Gauze/Linens
Sterilization Pouches, self-seal	2.25”x4”	57x(100+30)mm	0.004	0.0088	0.005
	2.25"x2.75"	57x(70+30)mm	0.004	0.0088	0.004
	2.75”x9”	70x(230+30)mm	0.020	0.04	0.02
	3.5”x6.5”	90x(135+30)mm	0.016	0.032	0.016
	3.5”x9”	90x(230+30)mm	0.024	0.12	0.024
	3.5”x10.5”	90x(270+30)mm	0.032	0.15	0.032
	3.5”x22”	90x(560+30)mm	0.072	0.32	0.072
	5”x15”	127x(380+30)mm	0.062	0.30	0.062
	5.25”x10”	135x(254+29)mm	0.045	0.22	0.045
	5.25”x10”	135x(255+30)mm	0.045	0.22	0.045
	5.25”x12”	135x(305+30)mm	0.052	0.26	0.05
	5.25”x13”	140x(330+30)mm	0.072	0.36	0.07
	6”x9”	150x(230+30)mm	0.055	0.27	0.05
	7.5”x13”	190x(330+30)mm	0.102	0.48	0.10
	8”x12.5”	200x(320+30)mm	0.12	0.53	0.10
	10”x14.5”	250x(370+30)mm	0.21	0.65	0.19
	10.6”x17”	270x(400+30)mm	0.38	0.78	0.22
	10.5”x17”	270x(430+30)mm	0.42	0.82	0.24
	12”x15”	300x(380+30)mm	0.52	0.90	0.23
	12”x16.5”	300x(420+30)mm	0.58	1.02	0.25
	12”x18”	300x(460+30)mm	0.68	1.10	0.28
	14”x19”	355x(480+30)mm	0.92	1.10	0.34
	15”x25”	380x(635+30)mm	1.30	1.10	0.50
	20"x22"	500x(560+40)mm	1.87	1.10	0.60
Sterilization Pouches, flat, heat seal	3.5”x22”	90x560mm	0.005	0.01	0.020
	4”x12”	100x300mm	0.004	0.0088	0.0176
	5”x15”	127x380mm	0.07	0.20	0.055
	6”x10”	150x254mm	0.06	0.19	0.05
	6”x22”	150x560mm	0.12	0.32	0.10

	7.5”x13”	190x330mm	0.10	0.25	0.09
	8”x20”	200x500mm	0.12	0.53	0.10
	12”x15”	300x380mm	0.44	0.54	0.38
	12”x18”	300x460mm	0.58	0.74	0.52
	16.5”x22.5”	420x570mm	1.87	1.10	0.60
Sterilization Pouches, gusseted, heat seal	4”x12”	100x50x300mm	0.004	0.0088	0.0176
	4”x14”	100x50x360mm	0.02	0.04	0.025
	6”x16”	150x50x400mm	0.05	0.12	0.04
	6”x18”	150x50x460mm	0.06	0.18	0.06
	8”x20”	200x55x500mm	0.12	0.53	0.10
	8”x16”	200x55x400mm	0.12	0.48	0.10
	8”x19”	250x65x480mm	0.30	0.74	0.26
	12”x22”	300x80x550mm	1.15	0.98	0.40
	16.5”x22.5”	420x100x570mm	1.87	1.10	0.60
Sterilization Reels, flat, heat seal	3”	75mmx30.5m	0.02	0.04	0.02
	4”	100mmx30.5m	0.025	0.15	0.032
	6”	150mmx30.5m	0.06	0.27	0.07
	8”	200mmx30.5m	0.10	0.53	0.10
	10”	250mmx30.5m	0.12	0.53	0.10
	2”	50mm x 200m	0.004	0.0088	0.004
	2.15”	55mm x 200m	0.004	0.0088	0.005
	3”	75mm x 200m	0.02	0.04	0.002
	4”	100mm x 200m	0.025	0.08	0.035
	4.7”	120mm x 200m	0.04	0.10	0.04
	6”	150mm x 200m	0.06	0.20	0.06
	8”	200mm x 200m	0.12	0.38	0.08
	10”	250mmx200m	0.12	0.53	0.10
	12”	300mm x 200m	0.52	0.53	0.25
	14”	350mm x 200m	0.92	1.05	0.34
	16”	400mm x 200m	1.08	1.07	0.52
	18”	450mm x 200m	1.30	1.10	0.58
	20”	500mm x 200m	1.87	1.10	0.60
Sterilization Reels, gusseted,	4.15”	55mm x 100m	0.004	0.0088	0.004
	3”	75mm x 100m	0.02	0.04	0.04
	4”	100mm x 100m	0.05	0.15	0.08
	6”	150mm x 100m	0.07	0.20	0.10
	8”	200mm x 100m	0.12	0.53	0.10

heat seal	10”	250mm x 100m	0.12	0.53	0.10
	12”	300mm x 100m	1.15	0.98	0.40
	14”	350mm x 100m	1.35	1.0	0.50
	16”	400mm x 100m	1.65	1.03	0.58
	18”	450mm x 100m	1.87	1.10	0.60
	20”	500mm x 100m	1.87	1.10	0.60

7. Non-Clinical Test Conclusion

Performance testing and Biocompatibility assessment were conducted to verify that the subject device met all design specifications. The test results demonstrated that the subject device meet the following standards (included but not fully described):

- ASTM F88/F88M-2015, Standard Test Method for Seal Strength of Flexible Barrier Materials.(Sterility)
- ASTM F1929-2015 Standard Test Method for Detecting Seal Leaks in Porous Medical Package by Dye Penetration
- ASTM F 2096-2011（2019） Standard Test Method for Detecting Gross Leaks in Packaging by Internal Pressurization (Bubble Test)
- ISO 1924-2:2008 Paper and board — Determination of tensile properties.
- ASTM F 2251-13 Standard Test Method for Thickness Measurement of Flexible Packaging Material
- ISO 11140-1:2014 Sterilization of health care products. Chemical indicators. General requirements
- ISO 10993-1: Biological evaluation of medical devices Part 1: Evaluation and testing within a risk management process
- ISO 10993-5:2009 Biological evaluation of medical devices- Part 5: Tests for in vitro cytotoxicity
- ISO 10993-7:2008 Biological Evaluation of Medical Device- Part 7: Ethylene Oxide Sterilization Residuals
- ISO 10993-10:2010 Biological evaluation of medical device- Part 10: Tests for irritation and skin sensitization
- ISO 10993-12: Biological evaluation of medical devices Part 12: Sample preparation and reference materials
- ISO 11135：2014 Sterilization of health-care products — Ethylene oxide — Requirements for the development, validation and routine control of a sterilization process for medical devices.
- DIN58953-6-2010 Sterilization - Sterile supply - Part 6: Microbial barrier testing of packaging materials for medical devices which are to be sterilized.
- ISO17665-1:2006 Sterilization of health care products-Moist heat-Part1: requirements for the development, validation and routine control of a sterilization process for medical devices.

8. Technological Characteristic Comparison Table

ITEM	Subject Device	Predicate Device K221875	Comparison analysis
Product Code	FRG, JOJ	FRG, JOJ	same
Regulation No.	21 CFR 880.6850	21 CFR 880.6850	same
Class	II	II	same
Indication for Use	The Sterilization Pouches and Reels is intended to provide health care workers with an effective method to enclosed devices in a single or double pouch configuration by steam or ethylene oxide sterilization. The recommended sterilization cycle parameters are as follows: a) Steam sterilization at 132°C (270°F) for 4 minutes; Drying time of 20 minutes. b) Ethylene Oxide (EO) with a concentration of 800 mg/L at 55 °C (131 °F) and 40%-80% relative humidity for 6 hours. Aeration time of 7 days at 20°C (68 °F). The Sterilization Pouches and Reels is composed of medical grade paper and medical compound film, maintains the sterility of the enclosed devices for up to 12 months post Steam or EO gas sterilization, and before sterilization has a maximum shelf life of 5 years from the date of manufacture. The pouch's external chemical indicators are designed to indicate to the user that the pouch has undergone either a steam or EO Sterilization process. Sterilization indicators will change color according to the sterilization method (Steam, Ethylene oxide). The color of steam sterilization indicator changes from Pink before sterilization to Cocoa after sterilization. The color of Ethylene oxide sterilization indicator changes from Blue before sterilization to Golden Brown after sterilization. The maximum validated pouch load is 1.87 lbs. (850g); The maximum validated reel load is 1.87 lbs. (850 g)	The Sterilization Pouch and Roll are intended to provide health care workers with an effective method to enclose devices intended for sterilization in the Steam or via Ethylene Oxide (EO). The recommended sterilization cycles are as follows: • Steam Sterilization at 132°C (270°F) for 4 minutes; Drying time of 20 minutes. • Ethylene Oxide (EO) with a concentration of 800 mg/L at 55°C (131 ° F) and 40% to 90% relative humidity for 6 hours. Aeration time of 7 days at 20°C). The sterilization pouch and roll are made with medical grade paper and medical compound film. The sterilization pouch and roll maintains the sterility of the enclosed devices for up to 24 months post Steam or EO gas sterilization, and before sterilization has a maximum shelf life of 5 years from the date of manufacture. The pouch's external chemical ink indicators are designed to indicate to the user that the pouch has undergone either a steam or EO sterilization process. Sterilization indicator will change color according to the sterilization method (ethylene oxide, steam). Ethylene oxide sterilization indicator color change from Pink before sterilization to Yellow after sterilization. The steam sterilization indicator color change from Blue before sterilization to Dark Grey after sterilization.	Same

Material Composition	Composed of medical grade paper and medical compound film and printed with a chemical indicator bar that changed from Pink to Cocoa (Steam) or Blue to Golden Brown (EO) when exposed to Steam vapor or EO gas during process. "Sterilization Pouches, flat, self seal" type contains tape.	Composed of medical grade paper, medical compound film, EO and Steam Process Indicator.	Similar. The Pouches with tape were validated for their effectiveness and safety. The test results show that the pouches are as effective and safe as predicate device.
Sterilization Cycles	Steam sterilization at 132°C (270°F) for 4 minutes; Drying time of 20 minutes. Ethylene Oxide (EO) with a concentration of 800 mg/L at 55 °C (131 °F) and 40%-80% relative humidity for 6 hours. Aeration time of 7 days at 20°C (68 °F).	Steam Sterilization at 132°C (270°F) for 4 minutes; Drying time of 20 minutes. • Ethylene Oxide (EO) with a concentration of 800 mg/L at 55°C (131 ° F) and 40% to 90% relative humidity for 6 hours. Aeration time of 7 days at 20°C.	same
Dimensions	Length of Pouches ranges from 2.75″ to 25″; Width of Pouches ranges from 2.25″ to 20″; Length of Reels ranges from 30.5m (=1200.78″) to 200m (=7874.01″); Width of Reels ranges from 2″ to 20″; There are 72 sizes in total. Please refer to table of Comparison of Dimension for detailed information.	Length of Pouches ranges from 3.5″ to 17″; Width of Pouches ranges from 2.25″ to 12″; Length of Reels (or Rolls) ranges from 100m (=3937″) to 200m (=7874.01″); Width of Reels ranges from 2″ to 17.7″ There are 32 sizes in total. Please refer to table of Comparison of Dimension for detailed information.	Similar
Sterilant Penetration Efficiency	It meets the requirement of $SAL10^{-6}$	It meets the requirement of $SAL10^{-6}$	same
EO、ECH residue	Referring to ISO 10993-7:2008, EO<4mg, ECH<9mg	Referring to ISO 10993-7:2008, EO<4mg, ECH<9mg	same
Performance Testing			
Chemical Indicator (CI) Functionality and Endpoint	The sterilant penetrated through the pouch configuration and rendered the CI color the endpoint color.	The sterilant penetrated through the pouch configuration and rendered the CI color the endpoint color.	same
Device Design of Steam CI	It changes from Pink to Cocoa when exposed to Steam vapor.	The color of Chemical Indicator changes from Blue to dark grey, when exposed to Steam.	different
Device Design of EO gas CI	It changes from Blue to Golden Brown when exposed to EO gas during process.	The color of Chemical Indicator changes from Pink to Yellow, when exposed to Steam	different
Thickness Variations (mm) ASTM F 2251-13	Pass	Pass	same
Tensile strength ISO 1924-2:2008	Pass	Pass	same

Burst Strength (kPa) ASTM F1140	≥ 0.45 Psig（3.1Kpa） Pass	> 3.0 Kpa Pass	same
Bubble Leak Test ASTM F 2096-2011（2019）	No Leakage Pass	No Leakage Pass	same
Seal Peel Test (N/15mm) ASTM F88/F88M-2023	Min value= 1.89 Pass	Min value= 2.10 Pass	same
Dye penetration Test ASTM F1929-15	No Infiltration Pass	No Infiltration Pass	same
Microbial Barrier Test DIN 58953-6-2016	CFU = 0 Pass	CFU = 0 Pass	same
EO、ECH residue	Referring to ISO 10993-7:2008, EO<4mg, ECH<9mg	Referring to ISO 10993-7:2008, EO<4mg, ECH<9mg	same
End point stability testing results	… The color of chemical indicator for EO sterilization indicator ink is blue, and the color of chemical indicator for steam sterilization indicator ink is pink after 5 years shelf life before sterilization.	… The color of chemical indicator for EO sterilization indicator ink is Pink, and the color of chemical indicator for steam sterilization indicator ink is Blue after 5 years shelf life before sterilization.	same
	The color of chemical indicator for EO sterilization indicator ink is Golden Brown, and the color of chemical indicator for steam sterilization indicator ink is Pink after EO sterilized and 24 months shelf life.	The color of chemical indicator for EO sterilization indicator ink is Yellow, and the color of chemical indicator for steam sterilization indicator ink is Blue after EO sterilized and 24 months shelf life.	Similar
	The color of chemical indicator for EO sterilization indicator ink is Blue, and the color of chemical indicator for steam sterilization indicator ink is Cocoa after steam sterilized and 24 months shelf life.	The color of chemical indicator for EO sterilization indicator ink is Pink, and the color of chemical indicator for steam sterilization indicator ink is Dark Grey after steam sterilized and 24 months shelf life.	Similar
Maintenance of Sterility	12 months	24months	Different but validated for its effectiveness
Shelf Life	5 years from date of manufacture	5 years from date of manufacture for EO and Steam Indicators	same
Biocompatibility	non-cytotoxic, non-irritative and non-sensitive to skin and conforming with ISO10993-1, ISO10993-5, ISO10993-7, ISO10993-10, ISO10993-12	non-cytotoxic, non-irritative and non-sensitive to skin and conforming with ISO10993-1,ISO10993-5, ISO10993-10, ISO10993-11	same. Tests result showed that the subject device is non-cytotoxic, non-irritative and non-sensitive to skin

Comparison of Dimension							
Subject device				Predicate device			
Model	Item	Specification Size (W×L)		Model	Item	Specification Size (W×L)	
	No.	Inch	Metric		No.	Inch	Metric mm×mm
Sterilization Pouches, self-seal	2001	2.25″×4″	57× (100+30) mm	PLANE-01 Sterilization Pouch	P-001	2.25″×3.5″	57×90
	2031	2.25″×2.75″	57× (70+30) mm		P-002	2.25″×4″	57×100
	2002	2.75″×9″	70× (230+30) mm		P-003	2.25″×5″	57×130
	2003	3.5″×6.5″	90× (135+30) mm		P-004	2.75″×10″	70×260
	2004	3.5″×9″	90× (230+30) mm		P-005	3.5″×5.25″	90×135
	2005	3.5″×10.5″	90× (270+30) mm		P-006	3.5″×6.5″	90×165
	2032	3.5″×22″	90× (560+30) mm		P-007	3.5″×10″	90×260
	2033	5″×15″	127× (380+30) mm		P-008	5.31″×10″	135×260
	2006	5.25″×10″	135× (254+29) mm		P-009	5.31″×11″	135×280
	2034	5.25″×10″	135× (255+30) mm		P-010	5.31″×13″	135×330
	2035	5.25″×12″	135× (305+30) mm		P-011	7.5″×14″	190×360
	2036	5.25″×13″	140× (330+30) mm		P-012	10″×14.5″	250×370
	2009	6″×9″	150× (230+30) mm		P-013	10.25″×16″	260×410
	2008	7.5″×13″	190× (330+30) mm		P-014	12″×17.7″	300×450
	2037	8″×12.5″	200× (320+30) mm	Roll-01 Sterilization Roll	R-101	2″	50mm×200m
	2009	10″×14.5″	250× (370+30) mm		R-102	3″	75mm×200m
	2010	10.6″×17″	270× (400+30) mm		R-103	4″	100mm×200m
	2038	10.5″×17″	270× (430+30) mm		R-104	6″	150mm×200m
	2039	12″×15″	300× (380+30) mm		R-105	8″	200mm×200m
	2012	12″×16.5″	300× (420+30) mm		R-106	10″	250mm×200m
	2011	12″×18″	300× (460+30) mm		R-107	12″	300mm×200m
	2040	14″×19″	355× (480+30) mm		R-108	14″	350mm×200m
	2041	15″×25″	380× (635+30) mm		R-109	16″	400mm×200m
	2042	20″×22″	500× (560+40) mm		R-110	17.7″	450mm×200m
Sterilization Pouches, flat, heat seal	2161	3.5″×22″	90×560mm		R-111	20″	500mm×200m
	2107	4″×12″	100×300mm	Roll-01 Sterilization Roll	GR-201	3″	75mm×100m
	2162	5″×15″	127×380mm		GR-202	4″	100mm×100m
	2163	6″×10″	150×254mm		GR-203	6″	150mm×100m
	2164	6″×22″	150×560mm		GR-204	8″	200mm×100m
	2165	7.5″×13″	190×330mm		GR-205	10″	250mm×100m
	2166	8″×20″	200×500mm		GR-206	12″	300mm×100m

	2167	12″×15″	300×380mm		GR-207	14″	350mm×100m
	2168	12″×18″	300×460mm		GR-208	16″	400mm×100m
	2169	16.5″×22.5″	420×570mm				
Sterilization Pouches, gusseted, heat seal	2406	4″×12″	100×50×300mm				
	2401	4″×14″	100×50×360mm				
	2402	6″×16″	150×50×400mm				
	2403	6″×18″	150×50×460mm				
	2404	8″×20″	200×55×500mm				
	2407	8″×16″	200×55×400mm				
	2408	8″×19″	250×65×480mm				
	2405	12″×22″	300×80×550mm				
	2409	16.5″×22.5″	420×100×570mm				
Sterilization Reels, flat, heat seal	2229	3″	75mm×30.5m				
	2230	4″	100mm×30.5m				
	2231	6″	150mm×30.5m				
	2232	8″	200mm×30.5m				
	2233	10″	250mm×30.5m				
	2201	2″	50mm × 200m				
	2211	2.15″	55mm × 200m				
	2202	3″	75mm × 200m				
	2203	4″	100mm × 200m				
	2210	4.7″	120mm × 200m				
	2204	6″	150mm × 200m				
	2205	8″	200mm × 200m				
	2206	10″	250mm×200m				
	2207	12″	300mm × 200m				
	2208	14″	350mm × 200m				
	2209	16″	400mm × 200m				
	2212	18″	450mm × 200m				
	2213	20″	500mm × 200m				
Sterilization Reels, gusseted, heat seal	2314	4.15″	55mm × 100m				
	2301	3″	75mm × 100m				
	2302	4″	100mm × 100m				
	2303	6″	150mm × 100m				
	2304	8″	200mm × 100m				
	2305	10″	250mm × 100m				
	2306	12″	300mm × 100m				
	2307	14″	350mm × 100m				
	2308	16″	400mm × 100m				
	2315	18″	450mm × 100m				
	2309	20″	500mm × 100m				

9. Clinical Test Conclusion

   No clinical study is included in this submission.

10. Conclusion

    The conclusions drawn from the nonclinical tests demonstrate that the subject device in 510(k) submission K242898, the Sterilization Pouches and Reels, is as safe, as effective, and performs as well as or better than the legally marketed predicate device cleared in K221875.