



December 12, 2025

Guangdong Maidi Medical Co., Ltd.
% Kiwi Xu
Official Correspondent
Shanghai SUNGO Management Consulting Co., Ltd.
14th Floor, Dongfang Building, 1500# Century Ave.
Shanghai,
China

Re: K251177

Trade/Device Name: Self-Seal Sterilization Pouch and Roll
Regulation Number: 21 CFR 880.6850
Regulation Name: Sterilization Wrap
Regulatory Class: Class II
Product Code: FRG, JOJ
Dated: November 13, 2025
Received: November 13, 2025

Dear Kiwi Xu:

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. Digitally signed by
ANISKO -S STEPHEN A. ANISKO -S
Date: 2025.12.12
14:55:05 -05'00'

Stephen Anisko
Acting 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

510(k) Number (if known)
K251177

Device Name
Self-Seal Sterilization Pouch and Roll

Indications for Use (Describe)

The Self-Seal 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 695 mg/L at 50°C (122°F) and 30% to 90% relative humidity for 4 hour. Aeration time of 7 days at room temperature.

The Self-Seal Sterilization Pouch and Roll are made with medical grade paper and medical compound film. The Self Sealing Sterilization Pouch and Roll maintains the sterility of the enclosed devices for up to 6 months post Steam or EO gas sterilization, and before sterilization has a maximum shelf life of 3 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 changes from red before sterilization to brown after sterilization. The steam sterilization indicator color changes from blue before sterilization to greenish black after sterilization.

Model	Product code	Specification (W*L)		Maximum load (lbs)		
		Inch	mm	Metal	Plastic	Gauze/Linens
Sterilization Pouch	WMDS.060-130	2 1/4" x 5"	60mm x 130mm	0.04	0.0057	0.005
	WMDS.070-183	2 3/4" x 7 1/5"	70mm x 183mm	0.07	0.03	0.005
	WMDS.070-260	2 3/4" x 10 1/4"	70mm x 260mm	0.09	0.08	0.07
	WMDS.075-185	3" x 7 3/10"	75mm x 185mm	0.12	0.1	0.08
	WMDS.090-170	3 1/2" x 6 3/4"	90mm x 170mm	0.12	0.11	0.09
	WMDS.090-230	3 1/2" x 9"	90mm x 230mm	0.13	0.12	0.11
	WMDS.090-260	3 1/2" x 10 1/4"	90mm x 260mm	0.14	0.13	0.11
	WMDS.120-190	4 7/10" x 7 1/2"	120mm x 190mm	0.21	0.2	0.12
	WMDS.130-260	5 1/10" x 10 1/4"	130mm x 260mm	0.48	0.39	0.19
	WMDS.135-290	5 1/4" x 11 1/2"	135mm x 290mm	0.5	0.4	0.21
	WMDS.150-230	6" x 9"	150mm x 230mm	0.56	0.4	0.21
	WMDS.180-272	7" x 10 7/10"	180mm x 272mm	0.58	0.42	0.22
	WMDS.195-360	7 3/4" x 14 1/4"	195mm x 360mm	0.6	0.43	0.23
	WMDS.240-320	9 2/5" x 12 3/5"	240mm x 320mm	1.94	0.46	0.24
	WMDS.250-400	9 4/5" x 15 3/4"	250mm x 400mm	3.34	0.48	0.26
	WMDS.300-400	11 4/5" x 15 3/4"	300mm x 400mm	3.34	0.69	0.3
	WMDS.390-400	15 3/10" x 15 3/4"	390mm x 400mm	3.34	0.8	0.32
WMDS.500-600	19 7/10" x 23 3/5"	500mm x 600mm	3.34	1.03	0.48	

Model	Product code	Specification (W*L)		Maximum load (lbs)		
		Inch	mm	Metal	Plastic	Gauze/Linens
Sterilization Roll	WMDR.055-200	2 1/5"	55mm×200m	0.07	0.03	0.003
	WMDR.075-200	3"	75mm×200m	0.09	0.05	0.004
	WMDR.100-200	4"	100mm×200m	0.14	0.13	0.11
	WMDR.150-200	6"	150mm×200m	0.55	0.53	0.5
	WMDR.200-200	8"	200mm×200m	0.6	0.58	0.55
	WMDR.250-200	10"	250mm×200m	1.06	1.05	0.62
	WMDR.350-200	12"	300mm×200m	0.6	0.58	0.55
	WMDR.300-200	14"	350mm×200m	1.06	1.05	0.62
	WMDR.400-600	16"	400mm×200m	1.08	1.06	0.63

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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510(k) Summary (K251177)

This summary of 510(k) safety and effectiveness information is being submitted in accordance with requirements of 21 CFR 807.92.

1.0 Submitter's Information

Name: Guangdong Maldi Medical Co., Ltd.
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Date Submitted: December 11, 2025.

Designated Submission Correspondent

Contact: Kiwi Xu
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2.0 Device Information

Trade/Device name: Self-Seal Sterilization Pouch and Roll
Common name: Sterilization Pouch and Roll
Regulation Name: 1) Sterilization Wrap;
2) Sterilization process indicator
Classification Product Code: 1) FRG;
Subsequent Product Code: 2) JOJ
Regulation number: 1) 21 CFR880.6850
2) 21 CFR880.2800
Classification: Class II
Panel: General Hospital

3.0 Predicate Device Information

Predicate Device:

Manufacturer: Qianjiang Kingphar Medical Packaging & Printing Co., Ltd.
Trade/Device Name: Sterilization Pouch and Roll
510(k) number: K221875

4.0 Device Description

The Self-Seal Sterilization Pouch and Roll is composed of medical grade paper (60g/m²) and PET/PP medical compound film (52 µm), it is intended to be used to contain medical devices to be terminally sterilized by the EtO or Steam sterilization process.

The recommended sterilization cycle parameter is:

- Steam Sterilization at 132°C (270°F) for 4 minutes; Drying time of 20 minutes.
- Ethylene Oxide (EO) with a concentration of 695 mg/L at 50°C (122°F) and 30% to 90% relative humidity for 4 hour. Aeration time of 7 days at room temperature.

The medical devices are inserted into the Pouch/Roll, sealed, and then sterilized for the EtO or Steam Sterilization Process. The pouch is self-sealed prior to sterilization processing. The roll is not self-sealed; use a plastic sealing machine to seal it, and the temperature of the plastic sealing machine needs to reach 205°C, After completion of the sterilization process, the Pouch/Roll maintain sterility of the enclosed medical devices until the seal is opened.

The device is intended to allow sterilization of enclosed devices and also to maintain sterility of the enclosed devices until used up to 6 months post sterilization.

The Pouch/Roll is printed with a chemical indicator bar that changes from blue to greenish black (Steam) or red to brown (EtO) when exposed to EtO gas or Steam vapor during process. The EtO and Steam Chemical Indicator offers 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 EtO and Steam Chemical Indicators do not signify sterilization; they only indicate that the indicator has been exposed to the EtO or Steam.

5.0 Indication for Use Statement

The Self-Seal 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 695 mg/L at 50°C (122°F) and 30% to 90% relative humidity for 4 hour. Aeration time of 7 days at room temperature.

The Self-Seal Sterilization Pouch and Roll are made with medical grade paper and medical compound film. The Self Sealing Sterilization Pouch and Roll maintains the

sterility of the enclosed devices for up to 6 months post Steam or EO gas sterilization, and before sterilization has a maximum shelf life of 3 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 changes from red before sterilization to brown after sterilization. The steam sterilization indicator color changes from blue before sterilization to greenish black after sterilization.

Table 1 Model and Dimension

Model	Product code	Specification (W*L)		Maximum load(lbs)		
		Inch	mm	Metal	Plastic	Gauze/Linens
Sterilization Pouch	WMDS.060-130	2 ¹ / ₄ "×5"	60mm × 130mm	0.04	0.0057	0.005
	WMDS.070-183	2 ³ / ₄ "×7 ¹ / ₅ "	70mm × 183mm	0.07	0.03	0.005
	WMDS.070-260	2 ³ / ₄ "×10 ¹ / ₄ "	70mm × 260mm	0.09	0.08	0.07
	WMDS.075-185	3"×7 ³ / ₁₀ "	75mm × 185mm	0.12	0.10	0.08
	WMDS.090-170	3 ¹ / ₂ "×6 ³ / ₄ "	90mm × 170mm	0.12	0.11	0.09
	WMDS.090-230	3 ¹ / ₂ "×9"	90mm × 230mm	0.13	0.12	0.11
	WMDS.090-260	3 ¹ / ₂ "×10 ¹ / ₄ "	90mm × 260mm	0.14	0.13	0.11
	WMDS.120-190	4 ⁷ / ₁₀ "×7 ¹ / ₂ "	120mm×190mm	0.21	0.20	0.12
	WMDS.130-260	5 ¹ / ₁₀ "×10 ¹ / ₄ "	130mm×260mm	0.48	0.39	0.19
	WMDS.135-290	5 ¹ / ₄ "×11 ¹ / ₂ "	135m × 290mm	0.50	0.40	0.21
	WMDS.150-230	6"×9"	150mm×230mm	0.56	0.40	0.21
	WMDS.180-272	7"×10 ⁷ / ₁₀ "	180mm×272mm	0.58	0.42	0.22
	WMDS.195-360	7 ³ / ₄ "×14 ¹ / ₄ "	195mm×360mm	0.60	0.43	0.23
	WMDS.240-320	9 ² / ₅ "×12 ³ / ₅ "	240mm×320mm	1.94	0.46	0.24
	WMDS.250-400	9 ⁴ / ₅ "×15 ³ / ₄ "	250mm×400mm	3.34	0.48	0.26
	WMDS.300-400	11 ⁴ / ₅ "×15 ³ / ₄ "	300mm×400mm	3.34	0.69	0.30
	WMDS.390-400	15 ³ / ₁₀ "×15 ³ / ₄ "	390mm×400mm	3.34	0.80	0.32
WMDS.500-600	19 ⁷ / ₁₀ "×23 ³ / ₅ "	500mm×600mm	3.34	1.03	0.48	
Sterilization Roll	WMDR.055-200	2 ¹ / ₅ "	55mm×200m	0.07	0.03	0.003
	WMDR.075-200	3"	75mm×200m	0.09	0.05	0.004
	WMDR.100-200	4"	100mm×200m	0.14	0.13	0.11
	WMDR.150-200	6"	150mm×200m	0.55	0.53	0.50
	WMDR.200-200	8"	200mm×200m	0.60	0.58	0.55
	WMDR.250-200	10"	250mm×200m	1.06	1.05	0.62
	WMDR.350-200	12"	300mm×200m	0.60	0.58	0.55
	WMDR.300-200	14"	350mm×200m	1.06	1.05	0.62
WMDR.400-600	16"	400mm×200m	1.08	1.06	0.63	

6.0 Technological Characteristic Comparison Table

Table 2 Comparison of Technology Characteristics

Item	Subject Device	Predicate Device	Comparison Analysis
Product Name	Self-Seal Sterilization Pouch And Roll	Sterilization Pouch and Roll	----
510(k) No.	K251177	K221875	----
Product Code	FRG,JOJ	FRG,JOJ	Same
Regulation No.	21 CFR 880.6850 21 CFR 880.2800	21 CFR 880.6850 21 CFR 880.2800	Same
Class	II	II	Same
Intended Use	<p>The Self-Seal 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:</p> <ul style="list-style-type: none"> • Steam Sterilization at 132°C (270°F) for 4 minutes; Drying time of 20 minutes. • Ethylene Oxide (EO) with a concentration of 695 mg/L at 50°C (122°F) and 30% to 90% relative humidity for 4 hour. Aeration time of 7 days at room temperature. The Self-Seal Sterilization Pouch and Roll are made with medical grade paper and medical compound film. The Self Sealing Sterilization Pouch and Roll maintains the sterility of the enclosed devices for up to 6 months post Steam or EO gas sterilization, and before sterilization has a maximum shelf life of 3 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 changes from red before sterilization to brown after sterilization. The steam sterilization indicator color changes from blue before sterilization to greenish black after sterilization. 	<p>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:</p> <ul style="list-style-type: none"> • 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 hour. 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 	Similar

		color change from Blue before sterilization to Dark Grey after sterilization.	
Material Composition	Composed of medical grade paper and medical compound film, EO and Steam Process Indicator	Composed of medical grade paper and medical compound film, EO and Steam Process Indicator	Same
Sterilization Cycles	<ul style="list-style-type: none"> • Steam Sterilization at 132°C (270°F) for 4 minutes; Drying time of 20 minutes. • Ethylene Oxide (EO) with a concentration of 695 mg/L at 50°C (122°F) and 30% to 90% relative humidity for 4 hour. Aeration time of 7 days at room temperature. 	<ul style="list-style-type: none"> • 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 hour. Aeration time of 7 days at 20°C). 	Different
Configuration/ Dimension	Various Size, Heat Sealing	Various Size, Heat Sealing	Same
Performance Testing			
Sterilant Penetration Efficacy	The test meet the requirement of SAL 10 ⁻⁶	The test meet the requirement of SAL 10 ⁻⁶	Same
Chemical Indicator (CI) Functionality and Endpoint	The sterilant penetrated through the pouch configuration and affected the CI color change to the endpoint color	The sterilant penetrated through the pouch configuration and affected the CI color change to the endpoint color	Same
Device Design of Steam CI	The color of Chemical Indicator changes from Blue to dark greenish black, when exposed to Steam	The color of Chemical Indicator changes from Blue to dark grey, when exposed to Steam	Similar
Device Design of EO gas CI	The color of Chemical Indicator changes from red to brown, when exposed to EO gas	The color of Chemical Indicator changes from Pink to Yellow, when exposed to EO gas	Similar
Thickness Variations (mm) ASTM F 2251	Passed	Passed	Same
Tensile strength ISO 1924-2	Passed	Passed	Same
Burst Strength (kPa) ASTM F1140 ; ISO 11607-1	Passed	Passed	Same
Leak Test ASTM-F2096	Passed	Passed	
Seal Peel Test (N/15mm) ASTM F88/F88M ; ISO 11607-1	Passed	Passed	Same
Dye penetration Test ASTM F1929 ; ISO11607-1	No Infiltration Passed	No Infiltration Passed	Same
Microbial Barrier	Passed	Passed	Same

Test			
End point stability testing results	The color of chemical indicator for EO sterilization indicator ink is Red, and the color of chemical indicator for steam sterilization indicator ink is Blue after 3 year 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 year shelf life before sterilization.	Similar
	The color of chemical indicator for EO sterilization indicator ink is Brown, and the color of chemical indicator for steam sterilization indicator ink is Blue after EO sterilized and 6 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 Red, and the color of chemical indicator for steam sterilization indicator ink is dark greenish black after steam sterilized and 6 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	6 months	24 months	Different
Shelf Life	3 years from date of manufacture for EO and Steam Indicators	5 years from date of manufacture for EO and Steam Indicators	Different
Biocompatibility	Conform with ISO10993-1 (ISO10993-4, ISO10993-5, ISO10993-10, ISO10993-11, ISO10993-23)	Conform with ISO10993-1 (ISO10993-4, ISO10993-5, ISO10993-10, ISO10993-11)	Same

The comparison between the subject and predicate devices is based on the following:

- Same intended use
- Same indications for use
- Similar material types that meet ISO 10993 biocompatibility requirements
- Same sterilization methods (EO and Steam sterilization process)
- Same fundamental technology/principal of operation/user interface

The subject device and the predicate device are identical in most key safety and effectiveness technical characteristics, such as material composition, basic design, sterilization method principles, physical properties (such as sealing strength, burst strength, microbial barrier) and biocompatibility. However, as shown in the comparison table, there are some differences, mainly concentrated in chemical indicator color, sterilization cycle parameters and shelf life. The following briefly discusses these differences:

Color differences of chemical indicators:

Property: The color change of the indicator is a visual indication, and it falls under the category of appearance characteristics.

The color differences do not alter the core function of the indicator, which is to indicate exposure to a specific sterilization process (EO or steam) through clear, distinct, and observable color changes. Both color systems comply with the

requirements of ISO 11140-1 for chemical indicators and provide equivalent process monitoring capabilities. Users only need to interpret them according to the instructions on the respective equipment labels, without causing confusion or misjudgment.

Differences in sterilization cycle parameters:

The subject device has undergone independent sterilization process verification in accordance with ISO 11135 (EO) and ISO 17665-1 (steam) standards. The results demonstrated that it can achieve a sterilization assurance level of SAL 10^{-6} under the specified parameters.

Difference between shelf life:

Properties: The declaration for the aseptic preservation period of the subject device is 6 months (compared to 24 months), and the shelf life (before sterilization) is 3 years (compared to 5 years).

This statement is designed to meet market demands and actual usage patterns and is supported by sufficient test data.

The identified differences (indicator color, specific sterilization parameters, declaration period) are non-core characteristics or process adjustments supported by sufficient verification, nor do they change the basic nature or intended use of the equipment.

7.0 Summary of Non-Clinical Testing

Summary of non-clinical and performance testing bench testing was performed to evaluate the performance and functionality of the subject device against requirement specification. The test results demonstrated the subject device is confirmed to be safe and effective for the intended use. The conducted tests listed as below:

Table 3 Summary of Non-Clinical Testing

Test	Test Method	Acceptance Criteria	Results
Sterilization process validation	ISO 11135:2014	Ethylene oxide: 4 hours at 132 °C; relative humidity between 30%-90%; ethylene oxide concentration is 800 mg/L, 7 days aeration time at room temperature. SAL= 10^{-6}	Pass
	ISO 17665-1:2006; ISO TS 17665-2:2009	Steam; 4 minutes at 132°C; 20 minutes dry time. SAL= 10^{-6}	Pass

Test	Test Method	Acceptance Criteria	Results
EO Residuals	ISO 10993-7:2008	EO ≤ 4 mg/device ECH ≤ 9 mg/device	Pass
Cytotoxicity	ISO 10993-5:2009	Non-cytotoxic	Pass
Sensitization	ISO 10993-10:2021	Non-sensitizing	Pass
Irritation	ISO 10993-23:2021	Non-irritating	Pass
Physical Performance			
Thickness	ASTM F2251-2013(2023)	Plastic: 52µm±15% Paper: 90µm±15%	Pass
Tensile Strength	ISO 1924-2:2008	MD: ≥4.4kN/m CD: ≥2.2kN/m	Pass. All samples met the requirements for Machine Direction and Cross Direction.
Seal Strength	ASTM F88/F88M-2023	≥ 2.5N/15mm	Pass. All tested samples demonstrated seal strength greater than 2.5N/15mm.
Burst Strength	ASTM F1140/F1140M-13(R2020)	Burst value > 3 kPa	Pass. All samples withstood internal pressurization greater than 3 kPa.
Dye Penetration	ASTM F1929-2023	No channel or seal leak	Pass. No dye penetration was observed in the seal area.
Leak Test (Bubble)	ASTM F2096-11:2019	No leakage	Pass. No gross leaks were detected.
Microbial Barrier	ASTM F1608-2021	LRV ≥ 1.0	Pass. The Log Reduction Value (LRV) was greater than 1.0.
Chemical Indicator	ISO 11140-1:2014 Premarket Notification [510(k)] Submissions for Chemical Indicators - Guidance for Industry and FDA Staff FDA	Color change to endpoint Steam sterile:The color of Chemical Indicator changes from Blue to dark greenish black, when exposed to Steam; EO sterile:The color of Chemical Indicator changes from red to brown, when exposed to EO gas. Remain stable before use based on its shelf life. Maintain the endpoint stability of the color change after being in the presence of the sterilant.	Pass

Test	Test Method	Acceptance Criteria	Results
		Off-set (transference): Migration of the indicator agent through the substrate to the surface opposite the one to which the indicator agent was applied shall not occur before, during or after the sterilization process. In use, the indicator agent shall not offset or bleed, penetrate the substrate to which it is applied or materials in which it is in contact.	
Shelf Life & Maintenance			
Shelf Life	ASTM F1980-21	Maintain integrity after 3-year aging	Pass. Physical properties (Seal strength, Burst, Dye penetration) met acceptance criteria after aging.
Sterility Maintenance	Real-time Aging	Sterile after 6 months post-sterilization storage	Pass. Products remained sterile and package integrity was maintained after 6 months of storage following sterilization.

8.0 Summary of Clinical Testing

No clinical study is included in this submission.

9.0 Conclusion

The conclusions drawn from the non-clinical tests demonstrate that the subject device (Self-Seal Sterilization Pouch and Roll) is as safe, as effective, and performs as well as or better than the predicate device K221875.