June 26, 2025

Yichang Xinxin Paper Products Co., Ltd.
% Boyle Wang
Manager
Shanghai Truthful Information Technology Co., Ltd.
Room 1801, No. 161 East Lujiazui Rd., Pudong
Shanghai, 200120
China

Re: K243179
Trade/Device Name: Sterilization Pouch and Roll
Regulation Number: 21 CFR 880.6850
Regulation Name: Sterilization wrap
Regulatory Class: Class II
Product Code: FRG, JOJ
Dated: May 20, 2025
Received: May 20, 2025

Dear Boyle Wang:

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,

Christopher K. Dugard -S

Christopher K. Dugard, M.S.
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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

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

510(k) Number *(if known)*
K243179

Device Name
Sterilization Pouch and Roll

Indications for Use *(Describe)*
The Sterilization Pouch and Roll are intended to provide health care workers with an effective method to enclose devices intended for steam sterilization. The recommended sterilization cycle is as follows:
• Pre-vacuum Steam: 4 minutes at 132°C (270°F); 30 minutes dry time.

The sterilization pouch and roll are made with medical grade paper and medical compound film. The sterilization pouch and roll maintain the sterility of the enclosed devices for up to 6 months post steam sterilization. The pouch's external chemical ink indicators are designed to indicate to the user that the pouch has undergone a steam sterilization process. The steam sterilization indicator color will change from blue before sterilization to dark grey after sterilization.

Table of Maximum Load

Item	Size (W)	Size (L)	Content / Max Load (lbs)
PZF-001, PZF-002, PZF-003, PZF-004, PZF-005, PZF-006, PZF-007, PZF-008, PRF-002, PRF-003	Minimum: 55mm Maximum: 90mm	Minimum: 70mm Maximum: 280mm	Metal: 0.02 Plastic: 0.01
PZF-009, PZF-010, PZF-011, PZF-012, PZF-013, PZF-014, PZF-015, PZF-016, PZF-017, PZF-018, PZF-019, PRF-001, PRF-004, PRF-005, PRF-006, PRF-007, PRF-008, PRF-009	Minimum: 57mm Maximum: 300mm	Minimum: 183mm Maximum: 610mm	Metal: 0.27 Plastic: 0.23
PZF-020, PZF-021, PZF-022, PZF-023, PZF-024, PRF-010	Minimum: 300mm Maximum: 460mm	Minimum: 483mm Maximum: 635mm	Metal:2.92 Plastic:1.13
PRF-011 PRF-012	400mm 420mm	580mm 600mm	Metal :3.38 Plastic: 1.13
PRFJ-001, PRFJ-002, PRFJ-003, PRFJ-004, PRFJ-005, PRFJ-006	Minimum: 55mm Maximum: 180mm	30M	Metal :0.02 Plastic: 0.01
PRFJ-007, PRFJ-008, PRFJ-009, PRFJ-010	Minimum: 200mm Maximum: 350mm	30M	Metal :1.13 Plastic: 0.86
PRFJ-011	400mm	30M	Metal :6.24 Plastic: 2.99

Item	Size (W)	Size (H)	Size (L)	Content / Max Load (lbs)
LRF-001 LRF-002	100mm 150mm	40mm 50mm	300mm 400mm	Metal: 0.21 Plastic: 0.05
LRF-003 LRF-004	150mm 200mm	50mm 50mm	400mm 480mm	Metal: 1.18 Plastic: 0.87
LRF-005	300mm	70mm	500mm	Metal :3.78 Plastic: 1.82
LRFJ-001, LRFJ-002, LRFJ-003	Minimum: 75mm Maximum: 150mm	Minimum: 35mm Maximum: 50mm	100M	Metal :0.12 Plastic: 0.02
LRFJ-004, LRFJ-005, LRFJ-006, LRFJ-007	Minimum: 200mm Maximum: 350mm	Minimum: 50mm Maximum: 80mm	100M	Metal :1.68 Plastic: 0.87
LRFJ-008	400mm	80mm	100M	Metal :3.67 Plastic: 3.00

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

K243179

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:	Yichang Xinxin Paper Products Co., Ltd.
Address:	No. 308, Jianghan Avenue, Majiadian Street, Zhijiang City, Yichang City, Hubei Province, 443200, China.
Tel:	+86 18086241888
Contact:	Peng Xiao

Designated Submission Correspondent

Contact:	Mr. Boyle Wang
Name:	Shanghai Truthful Information Technology Co., Ltd.
Address:	Room 1801, No. 161 East Lujiazui Rd., Pudong Shanghai, 200120, China.
Tel:	+86-21-50313932
Email:	Info@truthful.com.cn
Date Submitted:	June 23, 2025

2.0 Device Information

Trade/Device name:	Sterilization Pouch and Roll
Common name:	Sterilization Pouch and Roll
Classification name:	1) Wrap, Sterilization 2) Indicator, Physical/Chemical Sterilization Process
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:	Sigma Medical Supplies Corp.
Trade/Device Name:	SIGMA Sterilization Pouch and Roll

510(k) number: K180661

4.0 Device Description

The subject Sterilization Pouch and Roll device has five types:

(1) Self-sealing sterilization pouches:

These pouches are made from a medical grade plastic film that is heat sealed on three sides. The fourth side has an adhesive strip that is used to seal the pouch. Release paper used in the pouch is a laminated sheet with composing structure of PE/paper/PE. It is a strip to cover the adhesive area and is released before seal the pouch. The medical grade paper conforms to recognized material standards and can be sterilized by steam. The Process Indicators Ink printed on the medical grade paper will exhibit a color change after the pouch is exposed to steam.

(2) Sterilization pouches, Flat:

These pouches have the same components with the Self-sealing sterilization pouches, except the fourth side is left opened instead of an adhesive strip and will be heat-sealed when using.

(3) Sterilization pouches, Gusseted:

These pouches are the same with the Sterilization pouches, flat, except that the plastic film is folded on both longest sides instead of flat. This design is convenient to enclose the medical devices with certain height.

(4) Sterilization rolls, Flat:

These rolls are made from a medical grade paper and plastic film that are heat sealed on opposite two sides. It will be cut into the suitable length and the opened sides will be heat-sealed. The indicators printed on the medical grade paper are the same with the self-sealing sterilization pouches.

(5) Sterilization rolls, Gusseted:

These rolls are the same with the flat sterilization roll, except that the plastic film is folded on both longest sides instead of flat. This design is convenient to enclose the medical devices with certain height.

The Sterilization pouch and roll is composed of medical grade paper (60g/m^2) and medical compound film (52μm), it is intended to be used to contain medical devices to be terminally sterilized by the Steam sterilization process. The recommended sterilization cycle parameters are:

Pre-vacuum Steam: 4 minutes at 132°C (270°F); 30 minutes dry time.

The medical devices are inserted into the Pouch/Roll, sealed, and then sterilized for the Steam Sterilization Process. The heat-sealed pouch/roll are heat sealed prior to sterilization processing. 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 to maintain sterility of the enclosed devices until used up to 6 months post sterilization. The shelf life of the device is 3 months.

The Pouch/Roll is printed with a chemical indicator bar that changes from Blue to Dark grey when exposed to steam during the sterilization process. The steam chemical Indicator offers an addition way to verity processing in the sterilization cycle. The endpoint stability of the chemical indicator color change to dark grey is 3 months. The chemical Indicator should be used in addition to, not in place of, the biological indicator. The steam chemical indicator does not signify sterilization; it only indicates that the indicator has been exposed to steam.

The following table (Table 1~5) lists the model numbers of the sterilization pouch and roll by model, dimensions, and content/max. load (lbs.):

Table 1-The Model of Self-sealing sterilization pouches

Item	Specification Size (W x L)		Primary Package Dimension	Content / Max Load (lbs)
No.	Inch	mm	mm	lbs
PZF-001	2.24"X2.76"	57mmX70mm	62X55X75	Metal: 0.02 Plastic: 0.01
PZF-002	2.17"X3.94"	55mmX100mm	60X55X105	Metal: 0.02 Plastic: 0.01
PZF-003	2.26"X5.12"	57.5mmX130mm	62X55X135	Metal: 0.02 Plastic: 0.01
PZF-004	2.26"X5.31"	57.5mmX135mm	62X55X140	Metal: 0.02 Plastic: 0.01
PZF-005	2.76"X10.24"	70mmX260mm	75X50X265	Metal: 0.02 Plastic: 0.01
PZF-006	3.54"X5.31"	90mmX135mm	95X50X140	Metal: 0.02 Plastic: 0.01
PZF-007	3.54"X6.5"	90mmX165mm	95X50X170	Metal: 0.02 Plastic: 0.01
PZF-008	3.54"X10.24"	90mmX260mm	95X50X265	Metal: 0.02 Plastic: 0.01
PZF-008	3.54"X12.36"	90mmX314mm	95X50X314	Metal :0.27 Plastic: 0.23
PZF-010	5.31"X10.04"	135mmX255mm	140X50X260	Metal: 0.27 Plastic :0.23
PZF-011	5.31"X7.2"	135mmX183mm	140X50X188	Metal :0.27 Plastic :0.23
PZF-012	5.31"X11.02"	135mmX280mm	140X50X285	Metal :0.27

				Plastic :0.23
PZF-013	5.31"X11.61"	135mmX295mm	140X50X300	Metal :0.27 Plastic :0.23
PZF-014	5.31"X13.19"	135mmX335mm	140X50X340	Metal :0.27 Plastic :0.23
PZF-015	5.91"X24.02"	150mmX610mm	155X50X615	Metal :0.27 Plastic :0.23
PZF-016	5.91"X14.17"	150mmX360mm	155X50X365	Metal :0.27 Plastic :0.23
PZF-017	7.87"X17.13"	200mmX435mm	205X50X440	Metal :0.27 Plastic :0.23
PZF-018	9.84"X15.55"	250mmX395mm	255X50X400	Metal :0.27 Plastic :0.23
PZF-019	11.81"X14.96"	300mmX380mm	305X50X385	Metal :0.27 Plastic :0.23
PZF-020	11.81"X19.49"	300mmX495mm	305X50X500	Metal :2.92 Plastic :1.13
PZF-021	14.02"X19.02"	356mmX483mm	360X50X488	Metal :2.92 Plastic :1.13
PZF-022	14.96"X25.0"	380mmX635mm	385X50X640	Metal :2.92 Plastic :1.13
PZF-023	15.35"X19.69"	390mmX500mm	395X50X505	Metal: 2.92 Plastic :1.13
PZF-024	18.11"X24.02"	460mmX610mm	465X50X610	Metal :2.92 Plastic: 1.13

Table 2-The Model of Sterilization pouches, Flat

Item	Specification Size (W x L)		Primary Package Dimension	Content / Max Load (lbs)
No.	Inch	mm	mm	Lbs
PRF-001	2.24"X22.83"	57mmX580mm	62X55X585	Metal :0.27 Plastic:0.23
PRF-002	1.95"X7.87"	75mmX200mm	80X55X205	Metal :0.02 Plastic: 0.01
PRF-003	1.95"X11.02"	75mmX280mm	80X55X285	Metal :0.02 Plastic: 0.01
PRF-004	3.94"X16.54"	100mmX420mm	105X50X425	Metal :0.27 Plastic: 0.23
PRF-005	5.91"X7.87"	150mmX200mm	155X50X205	Metal :0.27 Plastic: 0.23
PRF-006	5.94"X11.81"	150mmX300mm	155X50X305	Metal :0.27 Plastic: 0.23
PRF-007	5.94"X21.65"	150mmX550mm	155X50X555	Metal :0.27

				Plastic: 0.23
PRF-008	7.87"X16.54"	200mmX420mm	205X50X425	Metal :0.27 Plastic: 0.23
PRF-009	9.84"X14.17"	250mmX360mm	255X50X360	Metal :0.27 Plastic: 0.23
PRF-010	11.81"X20.08"	300mmX510mm	305X50X515	Metal :2.92 Plastic: 1.13
PRF-011	15.75"X22.83"	400mmX580mm	405X50X585	Metal :3.38 Plastic: 1.13
PRF-012	16.54"X23.62"	420mmX600mm	425X50X605	Metal :3.38 Plastic: 1.13

Table 3-The Model of Sterilization pouches, Gusseted

Item	Specification Size (W x L)		Primary Package Dimension	Content / Max Load (lbs)
No.	Inch	mm	mm	Lbs
LRF-001	3.94"X1.57"X 11.81"	100mmX40mm X300mm	105X90X305	Metal :0.21 Plastic: 0.05
LRF-002	5.91"X1.97"X 15.75"	150mmX50mm X400mm	155X100X405	Metal :0.21 Plastic: 0.05
LRF-003	7.87"X1.97"X 15.75"	200mmX50mm X400mm	205X100X405	Metal :1.18 Plastic: 0.87
LRF-004	9.84"X2.36"X 18.9"	250mmX60mm X480mm	255X110X485	Metal :1.18 Plastic: 0.87
LRF-005	11.81"X2.76" X19.69"	300mmX70mm X500mm	305X120X505	Metal :3.78 Plastic: 1.82

Table 4-The Model of Sterilization rolls, Flat

Item	Specification Size (W x L)		Primary Package Dimension	Content / Max Load (lbs)
No.	Inch	mm & M	mm	Lbs
PRFJ-001	2.17"X118.11"	55mmX30M	110X11.5X11.5	Metal :0.02 Plastic: 0.01
PRFJ-002	2.95"X118.11"	75mmX30M	150X11.5X11.5	Metal :0.02 Plastic: 0.01
PRFJ-003	3.94"X118.11"	100mmX30M	200X11.5X11.5	Metal :0.02 Plastic: 0.01
PRFJ-004	5.0"X118.11"	127mmX30M	250X11.5X11.5	Metal :0.02 Plastic: 0.01
PRFJ-005	5.9"X118.11"	150mmX30M	200X11.5X11.5	Metal :0.02 Plastic: 0.01
PRFJ-006	7.09"X118.11"	180mmX30M	250X11.5X11.5	Metal :0.02 Plastic: 0.01

PRFJ-007	7.87"X118.11"	200mmX30M	200X11.5X11.5	Metal :1.13 Plastic: 0.86
PRFJ-008	9.84"X118.11"	250mmX30M	250X11.5X11.5	Metal :1.13 Plastic: 0.86
PRFJ-009	11.81"X118.11"	300mmX30M	300X11.5X11.5	Metal :1.13 Plastic: 0.86
PRFJ-010	13.78"X118.11"	350mmX30M	350X11.5X11.5	Metal :1.13 Plastic: 0.86
PRFJ-011	15.75"X118.11"	400mmX30M	400X11.5X11.5	Metal :6.24 Plastic: 2.99

Table 5-The Model of Sterilization rolls, Gusseted

Item	Specification Size (W x L)		Primary Package Dimension	Content / Max Load (lbs)
No.	Inch	mm & M	mm	Lbs
LRFJ-001	2.95"X1.38"X 393.7"	75mmX35mmX 100M	383X383X77.5	Metal :0.12 Plastic: 0.02
LRFJ-002	3.94"X1.57"X 393.7"	100mmX40mm X100M	383X383X102.5	Metal :0.12 Plastic: 0.02
LRFJ-003	5.91"X1.97"X 393.7"	150mmX50mm X100M	383X383X152.5	Metal :0.12 Plastic: 0.02
LRFJ-004	7.87"X1.97"X 393.7"	200mmX50mm X100M	383X383X202.5	Metal :1.68 Plastic: 0.87
LRFJ-005	9.84"X2.36"X 393.7"	250mmX60mm X100M	383X383X127.5	Metal :1.68 Plastic: 0.87
LRFJ-006	11.81"X2.76" X393.7"	300mmX70mm X100M	383X383X152.5	Metal :1.68 Plastic: 0.87
LRFJ-007	13.78"X3.15" X393.7"	350mmX80mm X100M	383X383X177.5	Metal :1.68 Plastic: 0.87
LRFJ-008	15.75"X3.15" X393.7"	400mmX80mm X100M	383X383X202.5	Metal :3.67 Plastic: 3.00

5.0 Indication for Use Statement

The Sterilization Pouch and Roll are intended to provide health care workers with an effective method to enclose devices intended for steam sterilization. The recommended sterilization cycle is as follows:
• Pre-vacuum Steam: 4 minutes at 132°C (270°F); 30 minutes dry time.

The sterilization pouch and roll are made with medical grade paper and medical compound film. The sterilization pouch and roll maintain the sterility of the enclosed devices for up to 6 months post steam sterilization. The pouch's external chemical ink indicators are designed to indicate to the user that the pouch has undergone a steam sterilization process. The steam sterilization indicator color will change from blue before sterilization to dark grey after sterilization.

Table of Maximum Load:

Item	Size (W)	Size (L)	Content / Max Load (lbs)
PZF-001, PZF-002, PZF-003, PZF-004, PZF-005, PZF-006, PZF-007, PZF-008, PRF-002, PRF-003	Minimum: 55mm Maximum: 90mm	Minimum: 70mm Maximum: 280mm	Metal: 0.02 Plastic: 0.01
PZF-009, PZF-010, PZF-011, PZF-012, PZF-013, PZF-014, PZF-015, PZF-016, PZF-017, PZF-018, PZF-019, PRF-001, PRF-004, PRF-005, PRF-006, PRF-007, PRF-008, PRF-009	Minimum: 57mm Maximum: 300mm	Minimum: 183mm Maximum: 610mm	Metal: 0.27 Plastic: 0.23
PZF-020, PZF-021, PZF-022, PZF-023, PZF-024, PRF-010	Minimum: 300mm Maximum: 460mm	Minimum: 483mm Maximum: 635mm	Metal:2.92 Plastic:1.13
PRF-011 PRF-012	400mm 420mm	580mm 600mm	Metal :3.38 Plastic: 1.13
PRFJ-001, PRFJ-002, PRFJ-003, PRFJ-004, PRFJ-005, PRFJ-006	Minimum: 55mm Maximum: 180mm	30M	Metal :0.02 Plastic: 0.01
PRFJ-007, PRFJ-008, PRFJ-009, PRFJ-010	Minimum: 200mm Maximum: 350mm	30M	Metal :1.13 Plastic: 0.86
PRFJ-011	400mm	30M	Metal :6.24 Plastic: 2.99

Item	Size (W)	Size (H)	Size (L)	Content / Max Load (lbs)
LRF-001 LRF-002	100mm 150mm	40mm 50mm	300mm 400mm	Metal: 0.21 Plastic: 0.05
LRF-003 LRF-004	150mm 200mm	50mm 50mm	400mm 480mm	Metal: 1.18 Plastic: 0.87
LRF-005	300mm	70mm	500mm	Metal :3.78 Plastic: 1.82
LRFJ-001, LRFJ-002, LRFJ-003	Minimum: 75mm Maximum: 150mm	Minimum: 35mm Maximum: 50mm	100M	Metal :0.12 Plastic: 0.02
LRFJ-004, LRFJ-005, LRFJ-006, LRFJ-007	Minimum: 200mm Maximum: 350mm	Minimum: 50mm Maximum: 80mm	100M	Metal :1.68 Plastic: 0.87
LRFJ-008	400mm	80mm	100M	Metal :3.67 Plastic: 3.00

6.0 Technological Characteristic Comparison Table

Table 2- Comparison of Technology Characteristics

Item	Subject Device	Predicate Device	Comparison Analysis
Product Name	**Sterilization Pouch and Roll**	**SIGMA Sterilization Pouch and Roll**	**----**
510(k) No.	K243179	K180661	----
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	The Sterilization Pouch and Roll are intended to provide health care workers with an effective method to enclose devices intended for steam sterilization. The recommended sterilization cycle is as follows: • Pre-vacuum Steam: 4 minutes at 132°C (270°F); 30 minutes dry time. The sterilization pouch and roll are made with medical grade paper and medical compound film. The sterilization pouch and roll maintain the sterility of the enclosed devices for up to 6 months post steam sterilization. The pouch's external chemical ink indicators are designed to indicate to the user that the pouch has undergone a steam sterilization process. The steam sterilization indicator color will change from blue before sterilization to dark grey after sterilization.	The SIGMA sterilization pouch and roll are intended to provide health care workers with an effective method to enclose devices intended for sterilization in steam autoclaves and via Ethylene Oxide (EO). The recommended steam sterilization cycle parameters are 30 minutes at 121°C. The recommended EO sterilization cycle is 4 hours at 55°C with a relative humidity between 50%-85% and a sterilant concentration of 600 mg/L. Furthermore, the sterilization pouch and roll maintain the enclosed devices up until 3 years post EO gas sterilization and maintains the enclosed devices up until 6 months post Steam sterilization. Lastly, 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.	Similar

Item	Subject Device (K243179)	Predicate Device (K180661)	Comparison Analysis
Material Composition	Medical Grade Paper, CPP, PET, PU adhesive, Steam Process Indicator Print Ink	Medical Grade Paper, CPP, PET, PU adhesive, EO and Steam Process Indicator Print Ink	Same
Sterilization Cycles	• Pre-vacuum steam: 4 minutes at 132°C (270°F); 30 minutes dry time. .	• Steam sterilization cycle parameters are 30 minutes at 121℃. • EO sterilization cycle is 4 hours at 55 ℃ with a relative humidity between 50%-85% and a sterilant concentration of 600 mg/L.	Similar
Types	Self-sealing sterilization pouches, Sterilization pouches, Flat Sterilization pouches, Gusseted, Sterilization rolls, Flat Sterilization rolls, Gusseted	Self-sealing sterilization pouches Sterilization pouches, Flat Sterilization pouches, Gusseted Sterilization rolls, Flat Sterilization rolls, Gusseted	Same
Configuration/ Dimensions	Various Sizes, Heat Sealing	Various Sizes, Heat Sealing	Similar
Sterilant Penetration Efficacy	The test meets the requirement of SAL 10^{-6}	The tests 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 CI	The color of Chemical Indicator changes from Blue to dark grey, when exposed to Steam.	The color of Chemical Indicator changes from Blue to Greenish Black, when exposed to Steam.	Similar

Item	Subject Device (K243179)	Predicate Device (K180661)	Comparison Analysis
Thickness Variations (mm) ASTM F2251	Passed	Passed	Same
Tensile strength ISO 1924-2	Passed	Passed	Same
Burst Strength (kPa) ASTM F1140; ISO 11607-1	> 3.0 Kpa Passed	Passed	Same
Bubble Leak Test ASTM D3078-02(2013)	No Leakage Passed	Passed	Same
Seal Peel Test (N/15mm) ASTM F88/F88M; ISO 11607-1	Min value= 2.08 Passed	Passed	Same
Dye penetration Test ASTM F1929; ISO 11607-1	No Infiltration Passed	Passed	Same

Item	Subject Device (K243179)	Predicate Device (K180661)	Comparison Analysis
Microbial Barrier Test DIN 58953-6	Passed	Passed	Same
End point stability testing results	The color of chemical indicator is blue after 3 months before sterilization.	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 2-year shelf life before sterilization.	Similar
	The color of the chemical indicator is dark grey after 3 months post sterilization.	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 3 years shelf life	Similar
Maintenance of Sterility	6 months	3 years post EO gas sterilization 6 months post Steam sterilization	Different
Shelf Life	3 months from date of manufacture	3 years from date of manufacture for EO and Steam Indicators	Different
Biocompatibility	Conform with ISO 10993-1, ISO 10993-4, ISO 10993-5, ISO 10993-10, ISO 10993-23, ISO 10993-11.	Conform with ISO 10993 standards	Same

The technological characteristics of the subject device are identical to those of predicate device. The subject device has the same basic design as the predicate device.

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
- Similar steam sterilization method
- Same fundamental technology/principal of operation/user interface
- The sterilization parameters of the subject device are different than those of the predicate device, but the steam sterilization validation results fully meet the requirements of ISO 17665-1.

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.

Table 3: Performance testing summary – Bench

Test Item	Test Methodology	Acceptance Criteria or End Point	Results
Sterilant penetration/drying time	ISO 17665-1: 2006; ISO 17665-2: 2009	- Meets the requirement of SAL 10^{-6} - The weight difference before sterilization and after drying shall not exceed 3 %	Pass
Biocompatibility testing	ISO 10993-5:2009	Non-cytotoxic	Under conditions of the study, did not show potential toxicity to L-929 cells. Pass
	ISO 10993-23:2021	Non-irritating	Under the conditions of the study, not an irritant. Pass
	ISO 10993-10:2021	Non-sensitizing	Under conditions of the study, not a sensitizer. Pass

Test Item	Test Methodology	Acceptance Criteria or End Point	Results
Package Integrity / Material Compatibility /Sterility Maintenance	Package appearance ASTM F 1886-16	The appearance of the sterilization pouch is clean, intact and sealed on all four sides.	Pass
	Thickness ASTM F2251-13	52±12%μm	Pass
	Tensile strength of paper ISO 1924-2:2008	MD≥4.4 KN/m CD≥2.2 KN/m	Pass
	Bursting test ASTM F1140/F1140M-13	Burst value > 3 Kpa or No Burst	Pass
	Dye penetration test ASTM F1929-2023	The dye solution is no any leakage across the seal width of sterile barrier system. (No Infiltration)	Pass
	Seal strength test ASTM F88-2023	≧2.5N/ 15mm	Pass
	Vacuum leakage test ASTM D3078-02	No water can penetrate the sterilization pouch.	Pass
	Microbial barrier DIN 58953-6	0 CFU No growth	Pass
Chemical Indicator Testing	ISO 11140-1:2014	Color of indicator changes from blue to dark grey after Steam sterilization	Pass

Test Item	Test Methodology	Acceptance Criteria or End Point	Results
Chemical Indicator Testing	ISO 11140-1:2014	Shelf life: 3 months Endpoint stability: 3 months	Pass
Shelf life	ASTM F1980-21	Shelf life: 3 months	Pass

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 is as safe, as effective, and performs as well as the legally marketed predicated device, K180661.