January 28, 2026

STERIVIC Medical Co., Ltd.
℅ Ivy Wang
Consultant
Shanghai SUNGO Management Consulting Co., Ltd.
Room 1401, Dongfang Building, 1500# Century Ave.
Shanghai, SH 200122
China

Re: K251347
Trade/Device Name: Sterilization Pouch/Roll
Regulation Number: 21 CFR 880.6850, 21 CFR 880.2800
Regulation Name: Sterilization Wrap, Sterilization process indicator
Regulatory Class: Class II
Product Code: FRG, JOJ
Dated: December 29, 2025
Received: December 29, 2025

Dear Ivy 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,

STEPHEN A. ANISKO -S

Digitally signed by STEPHEN A. ANISKO -S
Date: 2026.01.28 17:54:00 -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

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)*
K251347

Device Name
Sterilization Pouch/Roll

Indications for Use *(Describe)*
The Sterilization Pouch/Roll is 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 Sterilization Pouch/Roll is made with medical grade paper and medical compound film. The Sterilization Pouch/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 change from Pink before sterilization to Yellow after sterilization. The steam sterilization indicator color change from Blue before sterilization to Black after sterilization.
The specification and recommended sterilization load of the device is following: see attached page

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.

The specification and recommended sterilization load of the device is following:

Type	Product code	Specification （W*L）		Content/Max Load （lbs）		
		Inch	mm*mm	Metal	Plastic	Gauze/ linens
Sterilization Pouch	SVSP-050090	1.96″×2.36″	50×90	0.015	0.015	0.002
	SVSP-050225	1.96″×7.68″	50×225	0.03	0.02	0.002
	SVSP-050250	1.96″×8.67″	50×250	0.03	0.02	0.004
	SVSP-050260	1.96″×9.05″	50×260	0.04	0.02	0.004
	SVSP-057090	2.24″×2.36″	57×90	0.02	0.015	0.005
	SVSP-057100	2.24″×2.76″	57×100	0.02	0.015	0.005
	SVSP-057130	2.24″×3.94″	57×130	0.04	0.02	0.006
	SVSP-060100	2.36″×2.76″	60×100	0.07	0.03	0.006
	SVSP-060110	2.36″×3.15″	60×110	0.07	0.03	0.006
	SVSP-060135	2.36″×4.13″	60×135	0.10	0.07	0.006
	SVSP-060200	2.36″×6.7″	60×200	0.27	0.13	0.006
	SVSP-070255	2.76″×8.86″	70×255	0.39	0.15	0.007
	SVSP-070260	2.76″×9.1″	70×260	0.40	0.15	0.007
	SVSP-075150	2.95″×4.7″	75×150	0.54	0.20	0.007
	SVSP-080160	3.15″×5.1″	80×160	0.66	0.30	0.007
	SVSP-090100	3.54″×2.76″	90×100	0.69	0.30	0.007
	SVSP-090150	3.54″×4.7″	90×150	0.72	0.40	0.008
	SVSP-090165	3.54″×5.3″	90×165	0.78	0.40	0.008
	SVSP-090180	3.54″×5.9″	90×180	0.81	0.48	0.008
	SVSP-090210	3.54″×7.1″	90×210	1.12	0.50	0.008
	SVSP-090230	3.54″×7.87″	90×230	1.14	0.50	0.008
	SVSP-090260	3.54″×9.1″	90×260	1.22	0.55	0.008
	SVSP-100200	4″×6.69″	100×200	1.43	0.68	0.009
	SVSP-100230	4″×7.87″	100×230	1.45	0.72	0.01
	SVSP-100300	4″×10.6″	100×300	1.53	0.86	0.01
	SVSP-110305	4.3″×6.9″	110×305	1.55	0.92	0.02
	SVSP-115165	4.5″×5.3″	115×165	1.48	1.04	0.03
	SVSP-115230	4.5″×7.87″	115×230	1.62	1.32	0.04
	SVSP-115305	4.5″×10.8″	115×305	1.65	1.50	0.04
	SVSP-135260	5.3″×9.1″	135×260	1.73	1.71	0.05
	SVSP-135280	5.3″×9.8″	135×280	1.75	1.73	0.05
	SVSP-135300	5.3″×10.6″	135×300	1.80	1.78	0.05
	SVSP-135360	5.3″×13″	135×360	1.83	1.81	0.06
	SVSP-140250	5.5″×8.7″	140×250	1.83	1.82	0.07

	SVSP-140305	5.5″×10.8″	140×305	1.94	1.89	0.07
	SVSP-150380	5.9″×13.8″	150×380	2.05	1.96	0.09
	SVSP-160200	6.3″×6.7″	160×200	2.08	2.02	0.05
	SVSP-160340	6.3″×12.2″	160×340	2.13	2.11	0.09
	SVSP-165255	6.5″×8.86″	165×255	2.24	2.21	0.09
	SVSP-190305	7.5″×10.8″	190×305	2.43	2.41	0.09
	SVSP-190330	7.5″×11.8″	190×330	2.44	2.44	0.10
	SVSP-190360	7.5″×13″	190×360	2.51	2.48	0.10
	SVSP-190380	7.5″×13.8″	190×380	2.53	2.51	0.10
	SVSP-200320	7.87″×11.4″	200×320	2.53	2.52	0.10
	SVSP-200360	7.87″×13″	200×360	2.53	2.54	0.11
	SVSP-200400	7.87″×14.6″	200×400	2.62	2.65	0.11
	SVSP-205400	8.07″×14.6″	205×400	2.62	2.65	0.11
	SVSP-220360	8.7″×13″	220×360	2.74	2.72	0.20
	SVSP-230395	9.1″×14.4″	230×395	2.95	2.92	0.28
	SVSP-230430	9.1″×15.7″	230×430	3.03	3.02	0.32
	SVSP-250375	9.8″×13.6″	250×375	3.32	3.31	0.32
	SVSP-250400	9.8″×14.6″	250×400	3.51	3.48	0.38
	SVSP-260410	10.2″×15″	260×410	3.72	3.68	0.38
	SVSP-300380	11.8″×13.8″	300×380	4.06	4.02	0.46
	SVSP-300385	11.8″×14″	300×385	4.10	4.06	0.46
	SVSP-300430	11.8″×15.7″	300×430	4.10	4.08	0.52
	SVSP-300450	11.8″×16.5″	300×450	4.52	4.50	0.58
	SVSP-305430	12″×15.7″	305×430	4.53	4.51	0.58
	SVSP-360360	14.2″×13″	360×360	4.84	4.82	0.58
	SVSP-400400	15.7″×14.6″	400×400	5.01	5.02	0.64
	SVSP-400535	15.7″×20″	400×535	5.25	5.22	0.64
	SVSP-400580	15.7″×21.7″	400×580	5.38	5.38	0.64
	SVSP-400600	15.7″×22.4″	400×600	5.42	5.40	0.64
Sterilization Roll	SVFR-050100	1.96″×3937″	50mm×100m	0.015	0.015	0.003
	SVFR-050200	1.96″×7874″	50mm×200m	0.015	0.015	0.003
	SVFR-055100	2.16″×3937′′	55mm×100m	0.02	0.02	0.006
	SVFR-055200	2.16′′×7874′′	55mm×200m	0.02	0.02	0.006
	SVFR-075100	2.95″×3937″	75mm×100m	0.40	0.40	0.01
	SVFR-075200	2.95″×7874″	75mm×200m	0.40	0.02	0.01
	SVFR-100100	4″×3937″	100mm×100m	1.25	1.18	0.02
	SVFR-100200	4″×7874″	100mm×200m	1.25	1.18	0.02

	SVFR-120100	4.7″×3937″	120mm×100m	1.44	1.42	0.04
	SVFR-120200	4.7″×7874″	120mm×200m	1.44	1.42	0.04
	SVFR-125100	4.9″×3937″	125mm×100m	1.52	1.51	0.06
	SVFR-125200	4.9″×7874″	125mm×200m	1.52	1.51	0.06
	SVFR-150100	5.9″×3937″	150mm×100m	1.98	1.92	0.08
	SVFR-150200	5.9″×7874″	150mm×200m	1.98	1.92	0.08
	SVFR-200100	7.87″×3937″	200mm×100m	2.56	2.52	0.10
	SVFR-200200	7.87″×7874″	200mm×200m	2.56	2.52	0.10
	SVFR-250100	9.8″×3937″	250mm×100m	3.08	3.01	0.08
	SVFR-250200	9.8″×7874″	250mm×200m	3.08	3.01	0.08
	SVFR-300100	11.8″×3937″	300mm×100m	3.24	3.05	0.10
	SVFR-300200	11.8″×7874″	300mm×200m	3.24	3.05	0.10
	SVFR-350100	13.78″×3937″	350mm×100m	3.36	3.31	0.10
	SVFR-350200	13.78″×7874″	350mm×200m	3.36	3.31	0.10
	SVFR-400100	15.75″×3937″	400mm×100m	3.52	3.49	0.25
	SVFR-400200	15.75″×7874″	400mm×200m	3.52	3.49	0.25
	SVFR-450100	17.7″×3937″	450mm×100m	4.12	4.08	0.30
	SVFR-450200	17.7″×7874″	450mm×200m	4.12	4.08	0.30
	SVFR-500100	19.69″×3937″	500mm×100m	4.56	4.56	0.40
	SVFR-500200	19.69″×7874″	500mm×200m	4.56	4.56	0.40
	SVFR-600100	23.62″×3937″	600mm×100m	5.20	5.03	0.40
	SVFR-600200	23.62″×7874″	600mm×200m	5.20	5.03	0.40
	SVFR-700100	27.56″×3937″	700mm×100m	5.20	5.07	0.50
	SVFR-700200	27.56″×7874″	700mm×200m	5.20	5.07	0.50
	SVFR-800100	31.5″×3937″	800m×100m	5.40	5.40	0.60
	SVFR-800200	31.5″×7874″	800mm×200m	5.40	5.40	0.60

510(K) Summary
(K251347)

Prepared date: 2026-01-22

1. Applicant Information:

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Email: zxfda@sungoglobal.com

2. Device Information

Trade Name: Sterilization Pouch/Roll
Model: Sterilization pouch, Sterilization roll
Common Name: Sterilization pouch/ roll

Regulatory Information
Classification Name: 1) Sterilization wrap; 2) Sterilization Process Indicator
Regulation Number: 1) 21 CFR 880.6850; 2)21 CFR 880.2800
Product Code: FRG; JOJ
Device Class: 2
Review Panel: General Hospital

3. Predicate device

Manufacturer: Qianjiang Kingphar Medical Packaging & Printing Co., Ltd.
Trade Name: Sterilization pouch and roll
510(k) Number: K221875

Reference device:
Manufacturer: Sigma Medical Supplies Corp.
Trade Name: SIGMA Sterilization Pouch and Roll
510(k) Number: K180661

4. Device Description

The Sterilization Pouch/Roll is composed of medical grade paper(60g/m2) and medical compound film(50μm), 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: 4 minutes at 132°C(270°F); 20 minutes dry time.

Ethylene oxide: 4 hours at 50 °C(122°F); relative humidity between 30%- 90%; ethylene oxide concentration is 695 mg/L, 7 days aeration time 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 heat-sealed by a plastic sealing machine. 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 Pink to yellow (EtO) or Blue to Black (Steam) when exposed to EtO gas or Steam vapor during process. The EtO and Steam Chemical Indicator offers an addition way to verity 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. Indications for use

The Sterilization Pouch/Roll is 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 Sterilization Pouch/Roll is made with medical grade paper and medical compound film. The Sterilization Pouch/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 change from Pink before sterilization to Yellow after sterilization. The steam sterilization indicator color change from Blue before sterilization to Black after sterilization.

The specification and recommended sterilization load of the device is following:

Type	Product code	Specification (W*L)		Content/Max Load (lbs)		
		Inch	mm*mm	Metal	Plastic	Gauze/

						linens
Sterilization Pouch	SVSP-050090	1.96″×2.36″	50×90	0.015	0.015	0.002
	SVSP-050225	1.96″×7.68″	50×225	0.03	0.02	0.002
	SVSP-050250	1.96″×8.67″	50×250	0.03	0.02	0.004
	SVSP-050260	1.96″×9.05″	50×260	0.04	0.02	0.004
	SVSP-057090	2.24″×2.36″	57×90	0.02	0.015	0.005
	SVSP-057100	2.24″×2.76″	57×100	0.02	0.015	0.005
	SVSP-057130	2.24″×3.94″	57×130	0.04	0.02	0.006
	SVSP-060100	2.36″×2.76″	60×100	0.07	0.03	0.006
	SVSP-060110	2.36″×3.15″	60×110	0.07	0.03	0.006
	SVSP-060135	2.36″×4.13″	60×135	0.10	0.07	0.006
	SVSP-060200	2.36″×6.7″	60×200	0.27	0.13	0.006
	SVSP-070255	2.76″×8.86″	70×255	0.39	0.15	0.007
	SVSP-070260	2.76″×9.1″	70×260	0.40	0.15	0.007
	SVSP-075150	2.95″×4.7″	75×150	0.54	0.20	0.007
	SVSP-080160	3.15″×5.1″	80×160	0.66	0.30	0.007
	SVSP-090100	3.54″×2.76″	90×100	0.69	0.30	0.007
	SVSP-090150	3.54″×4.7″	90×150	0.72	0.40	0.008
	SVSP-090165	3.54″×5.3″	90×165	0.78	0.40	0.008
	SVSP-090180	3.54″×5.9″	90×180	0.81	0.48	0.008
	SVSP-090210	3.54″×7.1″	90×210	1.12	0.50	0.008
	SVSP-090230	3.54″×7.87″	90×230	1.14	0.50	0.008
	SVSP-090260	3.54″×9.1″	90×260	1.22	0.55	0.008
	SVSP-100200	4″×6.69″	100×200	1.43	0.68	0.009
	SVSP-100230	4″×7.87″	100×230	1.45	0.72	0.01
	SVSP-100300	4″×10.6″	100×300	1.53	0.86	0.01
	SVSP-110305	4.3″×6.9″	110×305	1.55	0.92	0.02
	SVSP-115165	4.5″×5.3″	115×165	1.48	1.04	0.03
	SVSP-115230	4.5″×7.87″	115×230	1.62	1.32	0.04
	SVSP-115305	4.5″×10.8″	115×305	1.65	1.50	0.04
	SVSP-135260	5.3″×9.1″	135×260	1.73	1.71	0.05
	SVSP-135280	5.3″×9.8″	135×280	1.75	1.73	0.05
	SVSP-135300	5.3″×10.6″	135×300	1.80	1.78	0.05
	SVSP-135360	5.3″×13″	135×360	1.83	1.81	0.06
	SVSP-140250	5.5″×8.7″	140×250	1.83	1.82	0.07
	SVSP-140305	5.5″×10.8″	140×305	1.94	1.89	0.07
	SVSP-150380	5.9″×13.8″	150×380	2.05	1.96	0.09

	SVSP-160200	6.3″×6.7″	160×200	2.08	2.02	0.05
	SVSP-160340	6.3″×12.2″	160×340	2.13	2.11	0.09
	SVSP-165255	6.5″×8.86″	165×255	2.24	2.21	0.09
	SVSP-190305	7.5″×10.8″	190×305	2.43	2.41	0.09
	SVSP-190330	7.5″×11.8″	190×330	2.44	2.44	0.10
	SVSP-190360	7.5″×13″	190×360	2.51	2.48	0.10
	SVSP-190380	7.5″×13.8″	190×380	2.53	2.51	0.10
	SVSP-200320	7.87″×11.4″	200×320	2.53	2.52	0.10
	SVSP-200360	7.87″×13″	200×360	2.53	2.54	0.11
	SVSP-200400	7.87″×14.6″	200×400	2.62	2.65	0.11
	SVSP-205400	8.07″×14.6″	205×400	2.62	2.65	0.11
	SVSP-220360	8.7″×13″	220×360	2.74	2.72	0.20
	SVSP-230395	9.1″×14.4″	230×395	2.95	2.92	0.28
	SVSP-230430	9.1″×15.7″	230×430	3.03	3.02	0.32
	SVSP-250375	9.8″×13.6″	250×375	3.32	3.31	0.32
	SVSP-250400	9.8″×14.6″	250×400	3.51	3.48	0.38
	SVSP-260410	10.2″×15″	260×410	3.72	3.68	0.38
	SVSP-300380	11.8″×13.8″	300×380	4.06	4.02	0.46
	SVSP-300385	11.8″×14″	300×385	4.10	4.06	0.46
	SVSP-300430	11.8″×15.7″	300×430	4.10	4.08	0.52
	SVSP-300450	11.8″×16.5″	300×450	4.52	4.50	0.58
	SVSP-305430	12″×15.7″	305×430	4.53	4.51	0.58
	SVSP-360360	14.2″×13″	360×360	4.84	4.82	0.58
	SVSP-400400	15.7″×14.6″	400×400	5.01	5.02	0.64
	SVSP-400535	15.7″×20″	400×535	5.25	5.22	0.64
	SVSP-400580	15.7″×21.7″	400×580	5.38	5.38	0.64
	SVSP-400600	15.7″×22.4″	400×600	5.42	5.40	0.64
Sterilization Roll	SVFR-050100	1.96″×3937″	50mm×100m	0.015	0.015	0.003
	SVFR-050200	1.96″×7874″	50mm×200m	0.015	0.015	0.003
	SVFR-055100	2.16″×3937′′	55mm×100m	0.02	0.02	0.006
	SVFR-055200	2.16′′×7874′′	55mm×200m	0.02	0.02	0.006
	SVFR-075100	2.95″×3937″	75mm×100m	0.40	0.40	0.01
	SVFR-075200	2.95″×7874″	75mm×200m	0.40	0.02	0.01
	SVFR-100100	4″×3937″	100mm×100m	1.25	1.18	0.02
	SVFR-100200	4″×7874″	100mm×200m	1.25	1.18	0.02
	SVFR-120100	4.7″×3937″	120mm×100m	1.44	1.42	0.04
	SVFR-120200	4.7″×7874″	120mm×200m	1.44	1.42	0.04

	SVFR-125100	4.9″×3937″	125mm×100m	1.52	1.51	0.06
	SVFR-125200	4.9″×7874″	125mm×200m	1.52	1.51	0.06
	SVFR-150100	5.9″×3937″	150mm×100m	1.98	1.92	0.08
	SVFR-150200	5.9″×7874″	150mm×200m	1.98	1.92	0.08
	SVFR-200100	7.87″×3937″	200mm×100m	2.56	2.52	0.10
	SVFR-200200	7.87″×7874″	200mm×200m	2.56	2.52	0.10
	SVFR-250100	9.8″×3937″	250mm×100m	3.08	3.01	0.08
	SVFR-250200	9.8″×7874″	250mm×200m	3.08	3.01	0.08
	SVFR-300100	11.8″×3937″	300mm×100m	3.24	3.05	0.10
	SVFR-300200	11.8″×7874″	300mm×200m	3.24	3.05	0.10
	SVFR-350100	13.78″×3937″	350mm×100m	3.36	3.31	0.10
	SVFR-350200	13.78″×7874″	350mm×200m	3.36	3.31	0.10
	SVFR-400100	15.75″×3937″	400mm×100m	3.52	3.49	0.25
	SVFR-400200	15.75″×7874″	400mm×200m	3.52	3.49	0.25
	SVFR-450100	17.7″×3937″	450mm×100m	4.12	4.08	0.30
	SVFR-450200	17.7″×7874″	450mm×200m	4.12	4.08	0.30
	SVFR-500100	19.69″×3937″	500mm×100m	4.56	4.56	0.40
	SVFR-500200	19.69″×7874″	500mm×200m	4.56	4.56	0.40
	SVFR-600100	23.62″×3937″	600mm×100m	5.20	5.03	0.40
	SVFR-600200	23.62″×7874″	600mm×200m	5.20	5.03	0.40
	SVFR-700100	27.56″×3937″	700mm×100m	5.20	5.07	0.50
	SVFR-700200	27.56″×7874″	700mm×200m	5.20	5.07	0.50
	SVFR-800100	31.5″×3937″	800m×100m	5.40	5.40	0.60
	SVFR-800200	31.5″×7874″	800mm×200m	5.40	5.40	0.60

6. Technological Characteristics Comparison Table

Device	Subject Device	Predicate Device	Reference Device	Result
510K number	K251347	K221875	K180661	-
Product name	Sterilization Pouch/ Roll	Sterilization Pouch and Roll	SIGMA Sterilization Pouch and Roll	-
Classification	Class II	Class II	Class II	Same
Regulation	21 CFR 880.6850 21 CFR 880.2800	21 CFR 880.6850 21 CFR 880.2800	21 CFR 880.6850	Same
Product code	FRG; JOJ	FRG; JOJ	FRG	Same
Intended use/ Indications for use	The Sterilization Pouch/Roll is 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 Sterilization Pouch/Roll is made with medical grade paper and medical compound film. The Sterilization Pouch/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 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 hour. Aeration time of 7 days at 20℃). 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	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 auto claves and via Ethylene Oxide (EO). The recommended steam sterilization cycle parameters are 30 minutes at 121 ℃ . The recommended EO sterilization cycle is 4 hours at 55℃ with a relative humidity between 50%-85% and a sterilant concentration of 600 mg/L. Furthermore, the sterilization pouch and roll maintains the enclosed devices up until 3 years post EO gas sterilization and maintains	Similar

	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 Black after sterilization.	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.	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. The SIGMA sterilization pouch and roll is offered in the following 5 types: - Self-sealing sterilization pouches - Sterilization pouches, Flat - Sterilization pouches, Gusseted - Sterilization rolls, Flat - Sterilization rolls, Gusseted	
Material Composition	Medical Grade Paper, CPP, PET, PU adhesive, EO and Steam Process Indicator Print Ink	Composed of medical grade paper and medical compound film, EO and Steam Process Indicator	Medical Grade Paper, CPP, PET, PU adhesive, EO and Steam Process Indicator Print Ink	Same with reference 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 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.	• 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℃).	• 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	Different

Configuration/ dimension	Various size, heat sealing and self sealing	Various size, heat sealing	Various size, heat sealing and self sealing	Same with reference device
Performance testing				
Sterilant Penetration Efficacy	The test meet the requirement of SAL 10^{-6}	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	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 black, when exposed to Steam	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
Device Design of EO gas CI	The color of Chemical Indicator changes from Pink to Yellow, when exposed to EO gas	The color of Chemical Indicator changes from Pink to Yellow, when exposed to EO gas	The color changes from - Red to Yellow, when exposed to EO gas	Similar
Thickness Variations (mm) ASTM F 2251	Passed	Passed	Passed	Same
Tensile strength ISO 1924-2	Passed	Passed	Passed	Same
Burst Strength (kPa) ASTM F1140; ISO 11607-1	> 3.0 Kpa Passed	Passed	Passed	Same

Leak test **ASTM-F 2096**	No leakage Passed	Passed	Passed	Same
Seal strength (N/15mm) **ASTM F88/F88M**	Min value= 2.53 Passed	Passed	Passed	Same
Dye penetration Test **ASTM F1929 ;** **ISO 11607-1**	No Infiltration Passed	Passed	Passed	Same
Microbial Barrier Test	LRV ⩾ 1.0 (ASTM F1608) Passed	CFU = 0 (DIN 58953-6) Passed	Passed (DIN 58953-6)	Same
End point stability testing results	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 3 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 year shelf life 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 3 year shelf life before sterilization.	Similar
	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 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.	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.	
	The color of chemical indicator for EO sterilization indicator ink is Pink, the color of chemical indicator for steam sterilization indicator ink is 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	The color of chemical indicator for EO sterilization indicator ink is Red, and the color of chemical indicator for steam sterilization indicator ink is Greenish Black	

		shelf life.	after steam sterilized and 6 months shelf life.	
Maintenance of Sterility	6 months	24 months	3 years post EO gas sterilization 6 months post Steam sterilization	Similar
Shelf life	3 years from date of manufacture for EO and Steam Indicators	5 years from date of manufacture for EO and Steam Indicators	3 years from date of manufacture for EO and Steam Indicators	Same with reference device
Biocompatibility	Conform with ISO 10993 standards	Conform with ISO10993 standards	Conform with ISO10993 standards	Same

The technological characteristics of the subject device are similar 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
- 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 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 material composition, chemical indicator color, sterilization cycle parameters and shelf life. The following briefly discusses these differences:

- Material composition difference: Both subject device and predicate device consists of paper and compound film and chemical indicator, while the subject device has one more adhesive which is to seal the pouch. The biocompatibility tests were done to the subject device and its test results were positive.

- Chemical indicator color difference: Chemical indicator is to indicate exposure to a specific sterilization process (EO or steam) through clear, distinct, and observable color change. Although the indicator color is different, both chemical indicators comply with the requirements of ISO 11140-1 and provide equivalent process monitoring capabilities.
- Difference in Sterilization cycle parameters: The subject device has undergone independent sterilization process validation 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.
- Shelf-life difference: 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.

7. 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 conducted tests listed as below:

Test Item	Test Method	Acceptance Criteria	Test Results
Sterilization process validation	ISO 11135:2014	Ethylene Oxide (EO): 4 hours at 50°C (122°F) and 30% to 90% relative humidity with a concentration of 695 mg/L; 7 days aeration time at room temperature SAL=10-6	Pass
	ISO 17665-1:2006	Steam: 4 minutes at 132°C (270°F); 20 minutes drying time. SAL=10-6	Pass
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)	Paper:90±5μm Plastic:50±5μm	Pass
Tensile Strength	ISO 19244-2: 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.
Dy Penetration	ASTM F1929-2023	No penetration	Pass. No dye penetration was

			observed in the seal area.
Leak Test (Bubble)	ASTM F2096-11:2019	No leakage	Pass. No leakage was found
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	Color change to endpoint Steam sterile: The color of Chemical Indicator changes from Blue to Black, when exposed to Steam; EO sterile: The color of Chemical Indicator changes from Pink to Yellow, 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. 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.	Pass
Shelf Life & Sterility 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. Clinical Test Conclusion

No clinical study is included in this submission.

9. Conclusion

The conclusions drawn from the nonclinical tests demonstrate that the subject device is as safe, as effective, and performs as well as or better than the legally marketed predicate device K221875.