November 1, 2021

SterileRight Packaging Mfg., Inc.
℅ Uta Shih
Regulatory Affairs Manager
Sen Mu Technology Co., LTD.
15F-2, No.1, Lane 26, Mincyuan 1st Rd., Lingya District
Kaohsiung City, 802
Taiwan

Re: K212338
Trade/Device Name: SterileRight sterilization pouch and roll
Regulation Number: 21 CFR 880.6850
Regulation Name: Sterilization Wrap
Regulatory Class: Class II
Product Code: FRG, JOJ
Dated: July 28, 2021
Received: August 3, 2021

Dear Uta Shih:

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 (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 located 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.

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 803) for devices or postmarketing safety reporting (21 CFR 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 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 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,

Clarence W. Murray, III, PhD
Assistant Director
DHT4B: Division of Infection Control
and Plastic Surgery 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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K212338

Device Name

SterileRight Sterilization Pouch and Roll

Indications for Use *(Describe)*

The SterileRight 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:

- Gravity steam at 121°C (250°F) for 30 minutes; Drying time of 25 minutes.
- Pre-vacuum steam at 132°C (270°F) for 4 minutes; Drying time of 20 minutes.
- Ethylene Oxide (EO) with a concentration of 735 mg/L at 55°C (131°F) and 50% to 80% relative humidity for 60 minutes. Aeration time of 8 hours at 60°C (140°F).

The SterileRight provides the sterilization pouch and roll made with Paper/Film or Tyvek®/Film.

The SterileRight sterilization pouch and roll which are made with Paper 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.

The SterileRight sterilization pouch and roll which are made with Tyvek® is for EO gas sterilization only. It also maintains the sterility of the enclosed devices for up to 6 months post EO gas sterilization, and before sterilization has a maximum shelf life of 3 years from the date of manufacture.

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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The maximum validated pouch load is 3.3 pounds (1.49 kg).

Type	Size	Model
Paper/Film Sterilization Flat Roll	W: 50mm ~ 400mm L: ~ 200M	P01
Paper/Film Sterilization Gusseted Roll	W: 75mm ~ 400mm L: ~ 100M	P02
Paper/Film Self-seal Sterilization Pouch	W: 57mm ~ 300mm L: 133mm ~ 474mm	P03
Paper/Film Sterilization Pouch	W: 50mm ~ 400mm L: 100mm ~ 600mm	P04
Tyvek®/Film Sterilization Flat Roll	W: 50mm ~ 400mm L: ~ 200M	T01
Tyvek®/Film Sterilization Gusseted Roll	W: 75mm ~ 400mm L: ~ 100M	T02
Tyvek®/Film Self-seal Sterilization Pouch	W: 57mm ~ 300mm L: 133mm ~ 474mm	T03
Tyvek®/Film Sterilization Pouch	W: 50mm ~ 400mm L: 100mm ~ 600mm	T04

510 (k) Summary for K212338

Submitter's Information

Name:	Sterileright Packaging Mfg., Inc.
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Establishment Registration Number:	1st submission
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Date Prepared:	July 22, 2021

Device Name

Trade Name:	SterileRight Sterilization Pouch and Roll
Common/usual Name:	SterileRight Sterilization Pouch and Roll
Device Classification Names:	1) Wrap, Sterilization. 2) Indicator, Physical/Chemical Sterilization Process
Panel:	General Hospital
Classification Product Code: Subsequent Product Code:	1) FRG 2) JOJ
Device Classification:	Class II
Regulation Number:	1) 21 CFR 880.6850 2) 21 CFR 880.2800

Predicate Devices

The predicate device [510(k) Notification K102158, cleared August 02, 2011] is the SIGMA Sterilization Pouch and Roll.

Indications for Use

The SterileRight 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:

- Gravity steam at 121°C (250°F) for 30 minutes; Drying time of 25 minutes.
- Pre-vacuum steam at 132°C (270°F) for 4 minutes; Drying time of 20 minutes.
- Ethylene Oxide (EO) with a concentration of 735 mg/L at 55°C (131°F) and 50% to 80% relative humidity for 60 minutes. Aeration time of 8 hours at 60°C (140°F).

The SterileRight provide sterilization pouch and roll made with Paper/Film or Tyvek® /Film.

The SterileRight sterilization pouch and roll which are made with Paper 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.

The SterileRight sterilization pouch and roll which are made with Tyvek® is for EO gas sterilization only. It also maintains the sterility of the enclosed devices for up to 6 months post EO gas sterilization, and before sterilization has a maximum shelf life of 3 years from the date of manufacture.

The SterileRight sterilization pouch and roll is offered 8 types in the following:

- Paper/Film Sterilization Flat Roll
- Paper/Film Sterilization Gusseted Roll
- Paper/Film Self-seal Sterilization Pouch
- Paper/Film Sterilization Pouch
- Tyvek® /Film Sterilization Flat Roll
- Tyvek® /Film Sterilization Gusseted Roll
- Tyvek® /Film Self-seal Sterilization Pouch
- Tyvek® /Film Sterilization Pouch

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

Table 1. The model numbers of SterileRight sterilization pouch and roll (Type, Model and Dimension and Content/Max. Load)

Type	Description	Model	Dimension	Content / Max Load (lbs.)		
				Metal	Plastic	Gauze / Linens
P01	Paper/Film Sterilization Flat Roll (with EO, Steam Indicators)	P01-050030	50mm x 30m	0.04	0.03	0.01
		P01-075030	75mm x 30m	0.06	0.05	0.02
		P01-100030	100mm x 30m	0.22	0.19	0.09
		P01-150030	150mm x 30m	0.40	0.35	0.18
		P01-200030	200mm x 30m	0.63	0.57	0.28
		P01-250030	250mm x 30m	2.22	2.08	1.04
		P01-300030	300mm x 30m	2.64	2.64	1.32
		P01-350030	350mm x 30m	2.64	2.64	1.32
		P01-400030	400mm x 30m	2.64	2.64	1.32
		P01-050200	50mm x 200m	0.04	0.03	0.01
		P01-075200	75mm x 200m	0.06	0.05	0.02
		P01-100200	100mm x 200m	0.22	0.19	0.09
		P01-150200	150mm x 200m	0.40	0.35	0.18
		P01-200200	200mm x 200m	0.63	0.57	0.28
		P01-250200	250mm x 200m	2.22	2.08	1.04
		P01-300200	300mm x 200m	2.64	2.64	1.32
		P01-350200	350mm x 200m	2.64	2.64	1.32
		P01-400200	400mm x 200m	2.64	2.64	1.32
P02	Paper/Film Sterilization Gusseted Roll (with EO, Steam Indicators)	P02-075030	75mm x 30m	0.08	0.06	0.03
		P02-100030	100mm x 30m	0.13	0.09	0.05
		P02-150030	150mm x 30m	0.67	0.43	0.22
		P02-200030	200mm x 30m	1.13	0.71	0.36
		P02-250030	250mm x 30m	1.78	1.09	0.55
		P02-300030	300mm x 30m	3.30	3.30	1.65
		P02-350030	350mm x 30m	3.30	3.30	1.65
		P02-400030	400mm x 30m	3.30	3.30	1.65
		P02-075100	75mm x 100m	0.08	0.06	0.03
		P02-100100	100mm x 100m	0.13	0.09	0.05
		P02-150100	150mm x 100m	0.67	0.43	0.22
		P02-200100	200mm x 100m	1.13	0.71	0.36
		P02-250100	250mm x 100m	1.78	1.09	0.55
		P02-300100	300mm x 100m	3.30	3.30	1.65
		P02-350100	350mm x 100m	3.30	3.30	1.65
		P02-400100	400mm x 100m	3.30	3.30	1.65

Table 1. (Continued) The model numbers of SterileRight sterilization pouch and roll (Type, Model and Dimension and Content/Max. Load)

Type	Description	Model	Dimension	Content / Max Load (lbs.)		
				Metal	Plastic	Gauze / Linens
P03	Paper/Film Self-seal Sterilization Pouch (with EO, Steam Indicators)	P03-057133	57mm x 133mm	0.04	0.03	0.01
		P03-070257	70mm x 257mm	0.11	0.09	0.04
		P03-090162	90mm x 162mm	0.08	0.07	0.03
		P03-090257	90mm x 257mm	0.15	0.13	0.06
		P03-090594	90mm x 594mm	0.53	0.47	0.23
		P03-133391	133mmX391mm	0.50	0.45	0.22
		P03-135283	135mm x 283mm	0.31	0.27	0.14
		P03-180335	180mm x 335mm	0.64	0.57	0.29
		P03-190358	190mm x 358mm	0.78	0.70	0.35
		P03-200435	200mm x 435mm	1.18	1.08	0.54
		P03-300380	300mm x 380mm	1.88	1.76	0.88
		P03-300474	300mm x 474mm	2.64	2.63	1.32
P04	Paper/Film Sterilization Pouch (with EO, Steam Indicators)	P04-050100	50mm x 100mm	0.02	0.02	0.01
		P04-075150	75mm x 150mm	0.06	0.05	0.02
		P04-075200	75mm x 200mm	0.08	0.07	0.03
		P04-100200	100mm x 200mm	0.12	0.10	0.05
		P04-100550	100mm x 550mm	0.55	0.49	0.25
		P04-120250	120mm x 250mm	0.22	0.19	0.09
		P04-120280	120mm x 280mm	0.26	0.22	0.11
		P04-150200	150mm x 200mm	0.22	0.19	0.09
		P04-150250	150mm x 250mm	0.30	0.26	0.13
		P04-150380	150mm x 380mm	0.58	0.52	0.26
		P04-150550	150mm x 550mm	1.08	0.99	0.49
		P04-180300	180mm x 300mm	0.54	0.48	0.24
		P04-200330	200mm x 330mm	0.74	0.67	0.33
		P04-200600	200mm x 600mm	2.06	1.93	0.96
		P04-205400	205mm x 400mm	1.07	0.98	0.49
		P04-250300	250mm x 300mm	0.92	0.83	0.42
		P04-300380	300mm x 380mm	1.88	1.76	0.88
		P04-300460	300mm x 460mm	2.64	2.49	1.25
		P04-400600	400mm x 600mm	2.64	2.64	1.32

Table 1. (Continued) The model numbers of SterileRight sterilization pouch and roll (Type, Model and Dimension and Content/Max. Load)

Type	Description	Model	Dimension	Content / Max Load (lbs.)		
				Metal	Plastic	Gauze / Linens
T01	Tyvek®/Film Sterilization Flat Roll	T01-050060	50mm x 60m	0.04	0.03	0.01
		T01-075060	75mm x 60m	0.06	0.05	0.02
		T01-100060	100mm x 60m	0.22	0.19	0.09
		T01-150060	150mm x 60m	0.40	0.35	0.18
		T01-200060	200mm x 60m	0.63	0.57	0.28
		T01-250060	250mm x 60m	2.22	2.08	1.04
		T01-300060	300mm x 60m	2.64	2.64	1.32
		T01-350060	350mm x 60m	2.64	2.64	1.32
		T01-400060	400mm x 60m	2.64	2.64	1.32
		T01-050200	50mm x 200m	0.04	0.03	0.01
		T01-075200	75mm x 200m	0.06	0.05	0.02
		T01-100200	100mm x 200m	0.22	0.19	0.09
		T01-150200	150mm x 200m	0.40	0.35	0.18
		T01-200200	200mm x 200m	0.63	0.57	0.28
		T01-250200	250mm x 200m	2.22	2.08	1.04
		T01-300200	300mm x 200m	2.64	2.64	1.32
		T01-350200	350mm x 200m	2.64	2.64	1.32
		T01-400200	400mm x 200m	2.64	2.64	1.32
T02	Tyvek®/Film Sterilization Gusseted Roll	T02-075030	75mm x 30m	0.08	0.06	0.03
		T02-100030	100mm x 30m	0.13	0.09	0.05
		T02-150030	150mm x 30m	0.67	0.43	0.22
		T02-200030	200mm x 30m	1.13	0.71	0.36
		T02-250030	250mm x 30m	1.78	1.09	0.55
		T02-300030	300mm x 30m	3.30	3.30	1.65
		T02-350030	350mm x 30m	3.30	3.30	1.65
		T02-400030	400mm x 30m	3.30	3.30	1.65
		T02-075100	75mm x 100m	0.08	0.06	0.03
		T02-100100	100mm x 100m	0.13	0.09	0.05
		T02-150100	150mm x 100m	0.67	0.43	0.22
		T02-200100	200mm x 100m	1.13	0.71	0.36
		T02-250100	250mm x 100m	1.78	1.09	0.55
		T02-300100	300mm x 100m	3.30	3.30	1.65
		T02-350100	350mm x 100m	3.30	3.30	1.65
		T02-400100	400mm x 100m	3.30	3.30	1.65

Table 1. (Continued) The model numbers of SterileRight sterilization pouch and roll (Type, Model and Dimension and Content/Max. Load)

Type	Description	Model	Dimension	Content / Max Load (lbs.)		
				Metal	Plastic	Gauze / Linens
T03	Tyvek®/Film Self-seal Sterilization Pouch	T03-057133	57mm x 133mm	0.04	0.03	0.01
		T03-070257	70mm x 257mm	0.11	0.09	0.04
		T03-090162	90mm x 162mm	0.08	0.07	0.03
		T03-090257	90mm x 257mm	0.15	0.13	0.06
		T03-135283	135mm x 283mm	0.31	0.27	0.14
		T03-180335	180mm x 335mm	0.64	0.57	0.29
		T03-190358	190mm x 358mm	0.78	0.70	0.35
		T03-254408	254mm x 408mm	1.59	1.48	0.74
		T03-300380	300mm x 380mm	1.88	1.76	0.88
		T03-300474	300mm x 474mm	2.64	2.63	1.32
T04	Tyvek®/Film Sterilization Pouch	T04-050100	50mm x 100mm	0.02	0.02	0.01
		T04-100200	100mm x 200mm	0.12	0.10	0.05
		T04-150255	150mm x 255mm	0.31	0.27	0.14
		T04-150380	150mm x 380mm	0.58	0.52	0.26
		T04-190330	190mm x 330mm	0.68	0.61	0.31
		T04-200330	200mm x 330mm	0.74	0.67	0.33
		T04-250300	250mm x 300mm	0.92	0.83	0.42
		T04-300380	300mm x 380mm	1.88	1.76	0.88
		T04-300460	300mm x 460mm	2.64	2.49	1.25
		T04-400600	400mm x 600mm	2.64	2.64	1.32

Device Description

The medical devices are inserted into the SterileRight sterilization Pouch/Roll, sealed, and then sterilized in the Sterilization System. After completion of the sterilization process, the Pouch/Roll maintains the 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 Steam or EO gas sterilization.

The Self-seal pouch permits the sealing of the pouch without the need of heat-sealing equipment, while the heat-sealed pouches and rolls are heat-sealed prior to processing in the steam/or EO Sterilization.

The chemical indicators ink printed on the "medical grade paper" will exhibit a color change after the pouch is exposed to steam or ethylene oxide gas. The color of the Chemical Indicator changes from Pink to Brown/Black when exposed to Steam. And the color changes from Blue to Yellow/Brown, when exposed to EO gas.

The Chemical Indicator offers an additional 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 Chemical Indicators do not signify sterilization; they only indicate that the indicator has been exposed to Steam/or EO gas.

The SterileRight sterilization pouch and roll made with Tyvek® is for EO gas sterilization only. It also maintains the sterility of the enclosed devices for up to 6 months post EO gas sterilization.

Description of Technological Characteristics Comparison

A summary of the technological characteristics of the device subject of this premarket notification in comparison to those of the predicate devices is included in **Table 2.**

Table 2. Summary of the Proposed and Predicate Devices Technological Characteristics

Feature	Proposed device	Predicate device	Comparison	
Device name	**SterileRight sterilization pouch and roll**	SIGMA sterilization pouch and roll (K102158)		
Material Composition	• Medical Grade Paper, CPP, PET, adhesive, EO and Steam Process Indicator, Print Ink. • Tyvek® , PET, PE, adhesive.	Medical Grade Paper, CPP, PET, PU adhesive, EO and Steam Process Indicator, Print Ink.	Similar	The Proposed device provides extra Tyvek® material.
Intended use	The SterileRight 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: •Gravity steam at 121°C (250°F) for 30 minutes; Drying time of 25 minutes. •Pre-vacuum steam at 132°C (270°F) for 4 minutes; Drying time of 20 minutes. •Ethylene Oxide (EO) with a concentration of 735 mg/L at 55°C (131°F) and 50% to 80% relative humidity for 60 minutes. Aeration time of 8 hours at 60°C (140°F). The SterileRight provides the sterilization pouch and roll made with Paper/Film or Tyvek® /Film. The SterileRight sterilization pouch and roll which are made with Paper 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. The SterileRight sterilization pouch and roll which are made with Tyvek® is for EO gas sterilization only. It also maintains the sterility of the enclosed devices for up to 6 months post 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 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 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	The Steam sterilization of the proposed device increase by one cycle (Pre-vacuum 132°C/ 4 min). The parameters of EO gas sterilization are similar.

Table 2. (Continued) Summary of the Proposed and Predicate Devices Technological Characteristics

Feature	Proposed device: SterileRight sterilization pouch and roll	Predicate device: SIGMA sterilization pouch and roll (K102158)	Comparison	Note
Pouch Types	● Paper/Film Sterilization Flat Roll ● Paper/Film Sterilization Gusseted Roll ● Paper/Film Self-seal Sterilization Pouch ● Paper/Film Sterilization Pouch ● Tyvek® /Film Sterilization Flat Roll ● Tyvek® /Film Sterilization Gusseted Roll ● Tyvek® /Film Self-seal Sterilization Pouch ● Tyvek® /Film Sterilization Pouch	● Self-sealing sterilization pouches ● Sterilization pouches, Flat ● Sterilization pouches, Gusseted ● Sterilization rolls, Flat ● Sterilization rolls, Gusseted	Similar	The Proposed device provides extra types Tyvek® /Film Sterilization pouch and roll.
Device models (Configurations/Dimensions)	**Paper/Film Sterilization Flat Roll** Size: W: 50mm ~ 400mm, L: ~ 200M Model: P01	**Sterilization rolls, Flat** Size: W: 50 mm ~ 400 mm, L: ~ 200 M Model: SMFR	Same	
	Paper/Film Sterilization Gusseted Roll Size: W: 75mm ~ 400mm, L: ~ 100M Model: P02	**Sterilization rolls, Gusseted** Size: W: 75 mm ~ 400 mm, L: ~ 100M, H: 35 mm ~ 80 mm Model: SMGR	Similar	
	Paper/Film Self-seal Sterilization Pouch Size: W: 57mm ~ 300mm, L: 133mm ~ 474mm Model: P03	**Self-Sealing Sterilization Pouches** Size: W: 57 mm ~ 300 mm, L: 133 mm ~ 474 mm Model: SMSE	Same	
	Paper/Film Sterilization Pouch Size: W: 50mm ~ 400mm, L: 100mm ~ 600mm Model: P04	**Sterilization Pouches, Flat** Size: W: 75 mm ~ 300 mm, L: 200 mm ~ 500 mm Model: SMFP	Similar	
	N/A	**Sterilization Pouches Gusseted** Size: W: 100 mm ~ 300 mm, L: 30 mm ~ 500 mm, H:40 mm ~ 70 mm Model: SMGP	Different	The Predicate device provides one extra type.
	Tyvek® /Film Sterilization Flat Roll Size: W: 50mm ~ 400mm, L: ~ 200M Model: T01	**N/A**	Different	The Proposed device provides one extra type.
	Tyvek® /Film Sterilization Gusseted Roll Size: W: 75mm ~ 400mm, L: ~ 100M Model: T02	**N/A**	Different	The Proposed device provides one extra type.
	Tyvek® /Film Self-seal Sterilization Pouch Size: W: 57mm ~ 300mm, L: 133mm ~ 474mm Model: T03	**N/A**	Different	The Proposed device provides one extra type.
	Tyvek® /Film Sterilization Pouch Size: W: 50mm ~ 400mm, L: 100mm ~ 600mm Model: T04	**N/A**	Different	The Proposed device provides one extra type.

Table 2. (Continued) Summary of the Proposed and Predicate Devices Technological Characteristics

Feature	Proposed Device: SterileRight sterilization pouch and roll	Predicate device: SIGMA sterilization pouch and roll (K102158)	Comparison	Note
Steam Sterilization cycle	The recommended steam sterilization parameters are as follows: • Gravity steam at 121°C (250°F) for 30 minutes; Drying time of 25 minutes. • Pre-vacuum steam at 132°C (270°F) for 4 minutes; Drying time of 20 minutes.	The recommended steam sterilization parameters are 30 minutes at 121℃; Drying time of 30 minutes.	Similar	
EO gas Sterilization cycle	The recommended EO sterilization parameters is as follows: • EO with a concentration of 735 mg/L at 55°C (131°F) and 50% to 80% relative humidity for 60 minutes. Aeration time of 8 hours at 60°C (140°F).	The recommended EO sterilization cycle is 4 hours at 55℃ with a relative humidity between 50%-85% and a sterilant concentration of 600 mg/L.	Similar	
Design features	**Paper/Film Sterilization Flat Roll:** These rolls are made from medical-grade paper and plastic film that are heat-sealed on opposite two sides. It will be cut into a suitable length and the opened sides will be heat-sealed. The medical-grade paper conforms to recognized material standards and can be sterilized by steam or ethylene oxide gas. The Process Indicators Ink printed on the medical grade paper will exhibit a color change after the pouch is exposed to steam or ethylene oxide gas. **Paper/Film Sterilization Gusseted Roll:** These rolls are the same as 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 at a certain height. **Paper/Film Self-seal Sterilization Pouch:** These pouches are made from medical-grade paper and 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 composing the structure of PE/paper/PE. It is a strip to cover the adhesive area and is released before sealing the pouch. The medical-grade paper conforms to recognized material standards and can be sterilized by steam or ethylene oxide gas. The Process Indicators Ink printed on the medical grade paper will exhibit a color change after the pouch is exposed to steam or ethylene oxide gas. **Paper/Film Sterilization Pouch:** These pouches have the same components as the Self-sealing sterilization pouches, except the fourth side is left open instead of an adhesive strip and will be heat-sealed when using. **Tyvek® /Film Sterilization Flat Roll:** These rolls are made from Tyvek® and plastic film that are heat-sealed on opposite two sides. It will be cut into a suitable length and the opened sides will be heat-sealed. The Tyvek-Film Sterilization Flat Roll can be sterilized by ethylene oxide gas. **Tyvek® /Film Sterilization Gusseted Roll:** These rolls are the same as the Tyvek® 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 at a certain height. The Tyvek-Film Sterilization Gusseted Roll can be sterilized by ethylene oxide gas. **Tyvek® /Film Self-seal Sterilization Pouch:** These pouches are made from a Tyvek® and 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 composing the structure of PE/paper /PE. It is a strip to cover the adhesive area and is released before sealing the pouch. The Tyvek-Film Self-seal Sterilization Pouch can be sterilized by ethylene oxide gas. **Tyvek® /Film Sterilization Pouch:** These pouches have the same components as the Self-sealing sterilization pouches, except the fourth side is left open instead of an adhesive strip and will be heat-sealed when using. The Tyvek-Film Sterilization Pouch can be sterilized by ethylene oxide gas.	**Self-sealing sterilization pouches:** These pouches are made from a medical grade plastic film that is heat sealed on three sides. The forth 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 or ethylene oxide gas. The Process Indicators Ink printed on the medical grade paper will exhibit a color change after the pouch is exposed to steam or ethylene oxide gas. **Sterilization pouches, Flat:** These pouches has the same components with the Self-sealing sterilization pouches, except the forth side is left opened instead of an adhesive strip and will be heat-sealed when using. **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. **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. **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.	Similar	The Proposed device provides extra types Tyvek® /Film Sterilization pouch and roll.

Table 2. (Continued) Summary of the Proposed and Predicate Devices Technological Characteristics

Feature / **Performance Testing**		Proposed Device: SterileRight sterilization pouch and roll	Predicate Devices: SIGMA sterilization pouch and roll (K102158)	**Comparison**
Sterilant Penetration	**Half-Cycle 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 Pink to Brown/Black, 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 changes from Blue to Yellow/Brown, when exposed to EO gas.	The color changes from red to yellow, when exposed to EO gas.	Similar
Package Integrity (Physical Properties)	**Thickness Variations (mm)** *ASTM F 2251*	Passed	Passed	Same
	Tensile strength of paper* (kN/m; N/15mm) *ISO 1924-2*	Passed	Passed	Same
	Air permeance of paper* (µm /(Pa.s)) *ISO 5636-3*	Passed	Passed	Same
	Thickness Variation (µm;mm) *ASTM F2251*	Passed	Passed	Same
	Burst Strength (kPa**)** *ASTM F1140 ; ISO 11607-1*	Passed	Passed	Same
	Bubble Leak Test *ASTM D 3078 ; ASTM-F 2096*	Passed	Passed	Same
	Seal Peel Test (N/15mm) *ASTM F88/F88M ; ISO 11607-1*	Passed	Passed	Same
	Visual Inspection (Seal Integrity) *ASTM F1886/F1886M;*	Passed	Passed	Same
	Dye penetration Test *ASTM F 1929 ;ISO 11607-1*	Passed	Passed	Same
	Microbial Barrier Test *DIN 58953-6 ;or ASTM F 1608*	Passed	Passed	Same
	Toxicological Properties (Biocompatibility Test) *ANSI/AAMI/ISO 10993-10*	Passed	Passed	Same
	Accelerated Aging Test *(Durability) ASTM F 1980 ; ISO 11607-1*	Passed	Passed	Same
End Point / Post Processing Color Stability	**after Steam sterilization**	6 months	6 months	Same
	after EO sterilization	6 months	3 Years	Similar
Shelf Life	**Chemical Indicator (CI) Functionality**	3 Years	3 Years	Same
	Accelerated aging test	3 Years	3 Years	Same

*Note: *the test items were performed on materials of the products; therefore, there is no specification requirements.*

Summary of Non-Clinical Testing

The results of the SterileRight sterilization pouch and roll validation studies demonstrate that the sterilization pouches perform as intended. The results are summarized as following **Table 3**:

Table 3. Summary of Non-Clinical Testing

Test completed	Standards followed	Acceptance criteria	Results	
Sterilant Penetration/ Drying Time/ Aeration	ANSI/AAMI/ISO 17665-1:2006/(R)2013, "Sterilization Of Health Care Products -Moist Heat - Part 1: Requirements For The Development, Validation, And Routine Control Of A Sterilization Process For Medical Devices"	- Meet the requirement of SAL 10^{-6}, the test BI (the Steam processed) : No bacterial growth -The weight difference before sterilization and after drying shall not exceed 0 %	Using half-cycle and full-cycle analysis. Test BI: No bacterial growth Weight difference = 0% Visual are drying.	Pass
	ANSI/AAMI/ISO TIR 17665-2:2009 (R2016), "Sterilization Of Health Care Products - Moist Heat - Part 2: Guidance On The Application Of ANSI/AAMI/ISO 17665-1"			
	AAMI / ANSI / ISO 11135:2014, "Sterilization Of Health Care Products - Ethylene Oxide - Requirements For Development, Validation And Routine Control Of A Sterilization Process For Medical Devices".	Meet the requirement of SAL 10^{-6}, the test BI (the EO processed) : No bacterial growth	Using half-cycle analysis. Test BI: No bacterial growth	Pass
	ISO 10993-7:2008 (R) 2012, "Biological Evaluation of Medical Devices - Part 7: Ethylene Oxide Sterilization Residuals	EO < 4mg ECH < 9mg	EO < 0.03mg ECH < 0.10 mg	Pass
Biocompatibility testing	ISO 10993-10 Third Edition 2010-08-01, "Biological Evaluation of Medical Devices- Part 10: Tests for irritation and skin sensitization".	Irritation index : 0 Sensitization index : 0	Primary irritation index : 0 Sensitization index (Patch test reaction): 0 (No visible change).	Pass
Package Integrity/ Material Compatibility/ Sterility Maintenance	ANSI/AAMI/ISO 11607-1:2019 "Packaging for terminally sterilized medical devices- Part 1: Requirements for materials, sterile barrier systems and packaging systems"			
	ASTM F 2251-13, "Standard Test Method for Thickness Measurement of Flexible Packaging Material"	STD DEV. < 1	STD DEV. 0.8	Pass
	ASTM F1140/F1140M-13, "Standard Test Methods for Internal Pressurization Failure Resistance of Unrestrained Packages";	• Burst value > 3.2 Kpa or No Burst • Creep Test: Pass (Set Pressure > 40% of burst value.)	Minimum of Burst pressure = 6.4 (kPa)	Pass
	ASTM F1929-15, "Standard Test Method for Detecting Seal Leaks in Porous Medical Packaging by Dye Penetration"	The dye solution is no any leakage across the seal width of sterile barrier system. (No Infiltration)	No Infiltration	Pass
	ASTM F88/F88M-15, "Standard Test Method for Seal Strength of Flexible Barrier Materials"	Seal strength > 2.5 (N/15mm)	Minimum of Seal strength = 2.9	Pass
	ASTM F 1980-07, "Standard Guide for Accelerated Aging of Sterile Barrier Systems for Medical Devices";	• 3 years accelerated aging Incubation: Range of Actual Value: Temp: 60℃± 2℃, Incubated for 13.9 weeks under controlled conditions simulating the real time for storage of 3 years. • 6 months accelerated aging Incubation: Range of Actual Value: Temp: 60℃± 2℃, Incubated for 17 days under controlled conditions simulating the real time for post-steam/EO sterilization storage of 6 months.	• 3 years accelerated aging Incubation: Range of Actual Value: Temp: 60℃± 2℃, Incubated for 13.9 weeks under controlled conditions simulating the real time for storage of 3 years. • 6 months accelerated aging Incubation: Range of Actual Value: Temp: 60℃± 2℃, Incubated for 17 days under controlled conditions simulating the real time for post-steam/EO sterilization storage of 6 months.	Pass

Table 3. (Continued) Summary of Non-Clinical Testing

Test completed	Standards followed	Acceptance criteria	Results	
Package Integrity/ Material Compatibility/ Sterility Maintenance	ASTM F2096-11, "Standard Test Method For Detecting Gross Leaks In Packaging By Internal Pressurization (Bubble Test)	No Leakage	No Leakage	Pass
	DIN 58953-6, "Sterilization -Sterile supply-Part 6: Microbial barrier testing of packaging materials for medical devices which are to be sterilized"	CFU = 0	CFU = 0	Pass
Chemical Indicator Efficacy testing (Type 1 Indicators)	AAMI/ANSI/ISO 11140-1:2014 "Sterilization of Health Care Products-Chemical Indicators-Part 1: General Requirements" **Steam** The color of CI changes from Pink to Brown/Black, when exposed to Steam. **EO gas** The color of CI changes from Blue to Yellow/Brown, when exposed to EO gas.	**Steam** **Change the color:** • 121℃ / 2.0 min & 134℃/ 0.3 min: **Unacceptable result** • 121℃/10.0 min & 134℃/ 2.0 min: **Acceptable result** • Dry heat 140℃/30 min: **Unacceptable result**	• 121℃ / 2.0 min & 134℃/ 0.3 min: the result of color is Pink • 121℃/10.0 min & 134℃/ 2.0 min: the result of color is from Pink to Black • Dry heat 140℃/30 min: the result of color is Pink.	Pass
		EO gas **Change the color:** • EO gas Teat / 2 min : **Unacceptable result** • EO gas Teat /20 min: **Acceptable result** • Absence of EO gas / 90 min: **Unacceptable result**	• EO gas Teat / 2 min: the result of color is Blue. • EO gas Teat /20 min: the result of color is Yellow. • Absence of EO gas / 90 min: the result of color is Blue.	Pass
	1. Remain stable before use based on its shelf life. 2. Maintain the endpoint stability of the color change after being in the presence of the sterilant.	All performance attributes should maintain the original color : 3 years shelf life	The real-time test was carried out from March 15, 2018 to April 15, 2021 that demonstrates: the test group which exposed to Steam maintain the color of Black, the test group which exposed to EO maintain the color of Yellow, and the Control group maintain the original color from March 15, 2018 to April 15, 2021.	Pass

CONCLUSION

The conclusions drawn from the nonclinical tests demonstrate that SterileRight Sterilization Pouch and Roll is as safe, as effective, and performs as well as or better than the predicate K102158