Sigma Medical Supplies Corporation
% Uta Shih
Regulatory Affairs Manager
Sen Mu Technology Co., LTD.
I5F-2, No.I, Lane 26, Mincyuan 1st Rd., Lingya District,
Kaohsiung City, 802
Taiwan

Re: K202462
Trade/Device Name: SIGMA Sterilization Pouch and Roll
Regulation Number: 21 CFR 880.6850
Regulation Name: Sterilization Wrap
Regulatory Class: Class II
Product Code: FRG
Dated: August 21, 2020
Received: August 27, 2020

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,

for Clarence W. Murray, III, Ph.D.
Acting 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)*
K202462

Device Name
SIGMA sterilization pouch and roll

Indications for Use *(Describe)*
The SIGMA sterilization pouch and roll are intended to provide health care workers with an effective method to enclose devices intended for sterilization in the Steam Sterilizer and via Ethylene Oxide (EO). The recommended sterilization cycles are as follows:

- Gravity steam at 121°C (250°F) for 30 minutes; Drying time of 30 minutes.
- Gravity steam at 132°C (270°F) for 15 minutes; Drying time of 30 minutes.
- Gravity steam at 135°C (275°F) for 10 minutes; Drying time of 30 minutes.
- Pre-vacuum steam at 132°C (270°F) for 4 minutes; Drying time of 20 minutes.
- Pre-vacuum steam at 135°C (275°F) for 3 minutes; Drying time of 16 minutes.
- EO sterilization cycle is 4 hours at 55°C (131°F) 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 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 6 types:

- Self-sealing sterilization pouches
- Self-sealing sterilization multi pouches
- Sterilization pouches, Flat
- Sterilization pouches, Gusseted
- Sterilization rolls, Flat
- Sterilization rolls, Gusseted

Type of Use *(Select one or both, as applicable)*

☐ Prescription Use (Part 21 CFR 801 Subpart D) ☒ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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The maximum validated pouch load is 3.53 pounds (1.6 kg).

Type	Size	Model
Self-sealing sterilization pouches	L: 133 mm ~ 610 mm W: 57 mm ~ 460 mm	SMSE
Self-sealing sterilization multi pouches	L: 283 mm ~ 335 mm W: 90 mm ~ 240 mm	SMSE
Sterilization pouches, Flat	L: 150 mm ~ 600 mm W: 75 mm ~ 420 mm	SMFP
Sterilization pouches, Gusseted	L: 300 mm ~ 500 mm W: 100 mm ~ 300 mm H: 40 mm ~ 70 mm	SMGP
Sterilization rolls, Flat	L: 30.5M ~ 200 M W: 50 mm ~ 400 mm	SMFR
Sterilization rolls, Gusseted	L: ~100 M W: 75 mm ~ 400 mm H: 35 mm ~ 80 mm	SMGR

510(k) Summary for K202462

Submitter's Information

Name:	**SIGMA Medical Supplies Corp.**
Address:	No.34, Ding-Ping Road, Rui Fang Industrial Park, Rui Fang Dist., New Taipei City 224, Taiwan (R.O.C.)
Establishment Registration Number:	3004970050
Contact:	Isabel Tsai RA Legal & Regulatory Affairs Dept. 886-3-3748880 ext. 3561 email: Isabel.Tsai@Benqmaterials.com Or Ethan Lin Sr. Specialist Market Planning Sec. 886-3-3648880 ext. 3572 email: Ethan.Lin @sigma-medical.com.tw
Date Prepared:	August 21, 2020

Device Name

Trade Name:	SIGMA Sterilization Pouch and Roll
Common/usual Name:	SIGMA Sterilization Pouch and Roll
Device Classification Names:	1) Wrap, Sterilization. 2) Indicator, Physical/Chemical Sterilization Process
Panel:	General Hospital
Classification Product Code:	1) FRG
Subsequent Product Code:	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 K180661, cleared June 05, 2018] is the SIGMA Sterilization Pouch and Roll.

Manufacturer：SIGMA Medical Supplies Corp.

Product Code：1) FRG 2) JOJ
510(k) number：K180661

Indications for Use

The SIGMA sterilization pouch and roll are intended to provide health care workers with an effective method to enclose devices intended for sterilization in the Steam Sterilizer and via Ethylene Oxide (EO). The recommended sterilization cycles are as follows:

- Gravity steam at 121℃ (250℉) for 30 minutes; Drying time of 30 minutes.
- Gravity steam at 132℃ (270℉) for 15 minutes; Drying time of 30 minutes.
- Gravity steam at 135℃ (275℉) for 10 minutes; Drying time of 30 minutes.
- Pre-vacuum steam at 132℃ (270℉) for 4 minutes; Drying time of 20 minutes.
- Pre-vacuum steam at 135℃ (275℉) for 3 minutes; Drying time of 16 minutes.
- EO sterilization cycle is 4 hours at 55℃ (131℉) 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 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 6 types:

- Self-sealing sterilization pouches
- Self-sealing sterilization multi pouches
- Sterilization pouches, Flat
- Sterilization pouches, Gusseted
- Sterilization rolls,
- Flat Sterilization rolls, Gusseted

The defining characteristics of the 6 types are as follows:

- **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.
- **Self-sealing sterilization multi pouches:** These pouches have the same components as the Self-sealing sterilization pouches, except that the interior of the pouch is divided into several compartments for packaging multiple instruments separately.

- **Sterilization pouches, Flat:** These pouches have 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.

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

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

Type	Model	Dimension in S.I.	*Content / Max Load (lbs.)		
			Metal	Plastic	Linens and Gauze
Self-Sealing Sterilization Pouches	SMSE057133	57 mm × 133 mm	0.11	0.03	0.03
	SMSE070257	70 mm × 257 mm	0.39	0.11	0.10
	SMSE090162	90 mm × 162 mm	0.30	0.09	0.08
	SMSE090168	90 mm × 168 mm	0.32	0.09	0.08
	SMSE090257	90 mm × 257 mm	0.57	0.16	0.14
	SMSE090265	90 mm × 265 mm	0.59	0.17	0.15
	SMSE090594	90 mm × 594 mm	1.35	0.45	0.39
	SMSE133289	133 mm × 289 mm	1.00	0.33	0.28
	SMSE133391	133 mm × 391 mm	1.43	0.48	0.41
	SMSE135193	135 mm × 193 mm	0.67	0.19	0.17
	SMSE135283	135 mm × 283 mm	0.99	0.33	0.28
	SMSE180335	135 mm × 335 mm	1.20	0.40	0.34
	SMSE150610	150 mm × 610 mm	2.08	0.83	0.69
	SMSE190358	190 mm × 358 mm	1.75	0.64	0.54
	SMSE190365	190 mm × 365 mm	1.79	0.65	0.55
	SMSE200435	200 mm × 435 mm	2.00	0.80	0.67
	SMSE300380	300 mm × 380 mm	2.48	1.10	0.90
	SMSE300474	300 mm × 474 mm	2.63	1.50	1.17
	SMSE300485	300 mm × 485 mm	2.70	1.54	1.20
	SMSE303474	303 mm × 474 mm	2.66	1.52	1.18
	SMSE305416	305 mm × 416 mm	2.56	1.28	1.02
	SMSE356483	356 mm × 483 mm	2.88	1.92	1.44
	SMSE380635	380 mm × 635 mm	3.16	2.53	1.80
	SMSE460610	460 mm × 610 mm	3.40	2.83	2.00
Self-sealing Sterilization Multi Pouches	SMSE090283	90 mm × 283 mm	0.24	0.07	0.06
	SMSE097314	97 mm × 314 mm	0.31	0.09	0.08
	SMSE152314	152 mm × 314 mm	0.41	0.12	0.10
	SMSE228314	228 mm × 314 mm	0.64	0.18	0.16
	SMSE240335	240 mm × 335mm	0.78	0.22	0.20

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

Type	Model	Dimension in S.I.	*Content / Max Load (lbs.)		
			Metal	Plastic	Linens and Gauze
Sterilization Pouches, Flat	SMFP075150	75 mm × 150 mm	0.25	0.07	0.06
	SMFP075200	75 mm × 200 mm	0.36	0.10	0.09
	SMFP075300	75 mm × 300 mm	0.57	0.16	0.14
	SMFP100200	100 mm × 200 mm	0.55	0.16	0.14
	SMFP100300	100 mm × 300 mm	0.78	0.24	0.21
	SMFP100550	100 mm ×550 mm	1.32	0.44	0.33
	SMFP120250	120 mm × 250 mm	0.81	0.25	0.22
	SMFP120280	120 mm × 280 mm	0.92	0.28	0.25
	SMFP150200	150 mm × 200 mm	0.82	0.25	0.22
	SMFP150250	150 mm × 250 mm	1.07	0.33	0.29
	SMFP150300	150 mm × 300 mm	1.16	0.39	0.33
	SMFP150380	150 mm × 380 mm	1.51	0.50	0.43
	SMFP150550	150 mm × 550 mm	1.94	0.70	0.60
	SMFP180300	180 mm × 300 mm	1.44	0.48	0.41
	SMFP200330	200 mm × 330 mm	1.56	0.57	0.48
	SMFP200400	200 mm × 400 mm	1.94	0.70	0.60
	SMFP200600	200 mm × 600 mm	2.75	1.10	0.92
	SMFP205400	205 mm × 400 mm	2.48	1.10	0.90
	SMFP250300	250 mm × 300 mm	2.26	1.00	0.82
	SMFP250450	250 mm × 450 mm	2.61	1.04	0.87
	SMFP300380	300 mm × 380 mm	2.65	1.06	0.88
	SMFP300460	300 mm × 460 mm	2.98	1.49	1.19
	SMFP300500	300 mm × 500 mm	3.26	1.63	1.30
	SMFP420400	420 mm × 400 mm	3.32	2.21	1.66
	SMFP420600	420 mm × 600 mm	3.44	2.86	2.02
Sterilization Pouches, Gusseted	SMGP100300	100 mm × 40 mm ×300 mm	2.26	1.88	1.33
	SMGP150400	150 mm × 50 mm × 400 mm	2.55	2.13	1.50
	SMGP200400	200 mm × 50 mm × 400 mm	2.68	2.23	1.58
	SMGP250480	250 mm × 60 mm × 480 mm	3.06	2.55	1.80
	SMGP300500	300 mm × 70 mm × 500 mm	3.45	2.88	2.03

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

Type	Model	Dimension in S.I.	*Content / Max Load (lbs.)		
			Metal	Plastic	Linens and Gauze
Sterilization Rolls, Flat	SMFR 022	50 mm × 200 M	0.26	0.08	0.07
	SMFR902	50.8 mm × 200 M	0.27	0.08	0.07
	SMFR 032	75 mm × 200 M	0.57	0.16	0.14
	SMFR912	76.2 mm × 200 M	0.58	0.17	0.15
	SMFR 042	100 mm × 200 M	0.87	0.25	0.22
	SMFR922	101.6 mm × 200 M	0.89	0.26	0.22
	SMFR 062	150 mm × 200 M	1.40	0.47	0.40
	SMFR932	152.4 mm × 200 M	1.43	0.48	0.41
	SMFR 082	200 mm × 200 M	1.86	0.75	0.62
	SMFR942	203.2 mm × 200 M	1.90	0.76	0.63
	SMFR 102	250 mm × 200 M	2.41	0.96	0.80
	SMFR952	254 mm × 200 M	2.45	0.98	0.82
	SMFR 122	300 mm × 200 M	2.77	1.38	1.11
	SMFR962	304.8 mm × 200 M	2.82	1.41	1.13
	SMFR 142	350 mm × 200 M	3.28	1.64	1.31
	SMFR 162	400 mm × 200 M	3.53	2.36	1.77
	SMFR02-1	50.8 mm × 30.5 M	0.27	0.08	0.07
	SMFR03-1	76.2 mm × 30.5 M	0.58	0.17	0.15
	SMFR04-1	101.6 mm × 30.5 M	0.89	0.26	0.22
	SMFR06-1	152.4 mm × 30.5 M	1.43	0.48	0.41
	SMFR08-1	203.2 mm × 30.5 M	1.90	0.76	0.63
	SMFR10-1	254 mm × 30.5 M	2.45	0.98	0.82
Sterilization Rolls, Gusseted	SMGR 031	75 mm × 35 mm × 100 M	2.21	1.84	1.30
	SMGR 041	100 mm × 40 mm × 100M	2.26	1.88	1.33
	SMGR 061	150 mm × 50 mm × 100 M	2.47	2.06	1.45
	SMGR 081	200 mm × 50 mm × 100 M	2.56	2.13	1.51
	SMGR 101	250 mm × 60 mm × 100 M	2.73	2.27	1.61
	SMGR 121	300 mm × 70 mm × 100 M	2.93	2.44	1.73
	SMGR 141	350 mm × 80 mm × 100 M	3.17	2.64	1.87
	SMGR 161	400 mm × 80 mm × 100 M	3.32	2.76	1.95

Device Description

The SIGMA sterilization pouches and rolls are inserted into the Pouch/Roll, sealed, and then sterilized in the Sterilization System. 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 3 years post EO gas sterilization and maintains the enclosed devices up until 6 months post Steam sterilization.

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

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 Chemical Indicator changes from Blue to Greenish Black, when exposed to Steam. And the color changes from red to yellow, when exposed to EO gas.

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

Description of Comparison and Substantial Equivalence

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	**SIGMA sterilization pouch and roll (K202462)**	**SIGMA sterilization pouch and roll (K180661)**	
Material Composition	Medical Grade Paper, CPP, PET, PU adhesive, EO and Steam Process Indicator, Print Ink	Medical Grade Paper, CPP, PET, PU adhesive, EO and Steam Process Indicator, Print Ink	Same
Intended use	The SIGMA sterilization pouch and roll are intended to provide health care workers with an effective method to enclose devices intended for sterilization in the Steam Sterilizer and via Ethylene Oxide (EO). The recommended sterilization cycles are as follows: • Gravity steam at 121℃ for 30 min; Drying time of 30 min. • Gravity steam at 132℃ for 15 min; Drying time of 30 min. • Gravity steam at 135℃ for 10 min; Drying time of 30 min. • Pre-vacuum steam at 132℃ for 4 min; Drying time of 20 min. • Pre-vacuum steam at 135℃ for 3 min; Drying time of 16 min. • 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 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 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.	Only the Steam recommended sterilization cycles are different. The recommended Steam sterilization cycles of proposed device increase 4 types of sterilization cycle, which are Gravity 132℃/15 min, Gravity 135℃/10 min, Pre-vacuum 132℃/ 4 min and Pre-vacuum 135℃/ 3 min.

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

<table>
<tr><th>Feature</th><th>Subject device: SIGMA sterilization pouch and roll</th><th>Predicate devices: SIGMA sterilization pouch and roll (K180661)</th><th>Comparison</th></tr>
<tr><td>Pouch Types</td><td>● Self-sealing sterilization pouches
● Self-sealing sterilization multi pouches
● Sterilization pouches, Flat
● Sterilization pouches, Gusseted
● Sterilization rolls, Flat
● Sterilization rolls, Gusseted</td><td>● Self-sealing sterilization pouches
● Sterilization pouches, Flat
● Sterilization pouches, Gusseted
● Sterilization rolls, Flat
● Sterilization rolls, Gusseted</td><td>The proposed device increase one type of the sterilization pouch, which is "Self-sealing sterilization multi pouches".</td></tr>
<tr><td rowspan="6">Device models (Configurations/Dimensions)</td><td>Self-Sealing Sterilization Pouches
Size: L: 133 mm ~ 610 mm, W: 57 mm ~ 460 mm
Model: SMSE</td><td>Self-Sealing Sterilization Pouches
Size: L: 133 mm ~ 610 mm, W: 57 mm ~ 460 mm
Model: SMSE</td><td>Same</td></tr>
<tr><td>Self-Sealing Sterilization Multi Pouches
Size: L: 283 mm ~ 335 mm, W: 90 mm ~ 240 mm
Model: SMSE</td><td>N/A</td><td>The proposed device increase one type and the size is different.</td></tr>
<tr><td>Sterilization Pouches, Flat
Size: L: 150 mm ~ 600 mm, W: 75 mm ~ 420 mm
Model: SMFP</td><td>Sterilization Pouches, Flat
Size: L: 150 mm ~ 600 mm, W: 75 mm ~ 420 mm
Model: SMFP</td><td>Same</td></tr>
<tr><td>Sterilization pouches, Gusseted
Size: L: 300 mm ~ 500 mm, W: 100 mm ~ 300 mm, H: 40 mm ~ 70 mm
Model: SMGP</td><td>Sterilization pouches, Gusseted
Size: L: 300 mm ~ 500 mm, W: 100 mm ~ 300 mm, H: 40 mm ~ 70 mm
Model: SMGP</td><td>Same</td></tr>
<tr><td>Sterilization rolls, Flat
Size: L: 30.5M ~ 200 M, W: 50 mm ~ 400 mm
Model: SMFR</td><td>Sterilization rolls, Flat
Size: L: 30.5M ~ 200 M, W: 50 mm ~ 400 mm
Model: SMGP</td><td>Same</td></tr>
<tr><td>Sterilization Rolls, Gusseted
Size: L: ~100 M, W: 75 mm ~ 400 mm, H: 35 mm ~ 80 mm
Model: SMGR</td><td>Sterilization Rolls, Gusseted
Size: L: ~100 M, W: 75 mm ~ 400 mm, H: 35 mm ~ 80 mm
Model: SMGR</td><td>Same</td></tr>
</table>

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

Feature	Subject devices: SIGMA sterilization pouch and roll (K202462)	Predicate devices: SIGMA sterilization pouch and roll (K180661)	Comparison
Steam Sterilization cycle	The recommended steam sterilization cycle parameters are as follows: • Gravity steam at 121℃ for 30 min; Drying time of 30 min. • Gravity steam at 132℃ for 15 min; Drying time of 30 min. • Gravity steam at 135℃ for 10 min; Drying time of 30 min. • Pre-vacuum steam at 132℃ for 4 min; Drying time of 20 min. • Pre-vacuum steam at 135℃ for 3 min; Drying time of 16 min.	The recommended steam sterilization cycle parameters are 30 minutes at 121℃; Drying time of 30 minutes.	The recommended Steam sterilization cycles of proposed device increase 4 types of sterilization cycle, which are Gravity 132℃/15 min, Gravity 135℃/10 min, Pre-vacuum 132℃/ 4 min and Pre-vacuum 135℃/ 3 min.
EO gas Sterilization cycle	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.	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.	Same
Design features	**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. **Self-sealing sterilization multi pouches:** These pouches have the same components as the Self-sealing sterilization pouches, except that the interior of the pouch is divided into several compartments for packaging multiple instruments separately. **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.	**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.	The proposed device increase one type of the sterilization pouch, which is "Self-sealing sterilization multi pouches". These pouches have the same components as the Self-sealing sterilization pouches, except that the interior of the pouch is divided into several compartments for packaging multiple instruments separately.
Steam CI Device Design	The color of Chemical Indicator changes from Blue to Greenish Black, when exposed to Steam.	The color of Chemical Indicator changes from Blue to Greenish Black, when exposed to Steam.	Same
EO gas CI Device Design	The color changes from red to yellow, when exposed to EO gas.	The color changes from red to yellow, when exposed to EO gas.	Same

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

Feature		Proposed Device: SIGMA sterilization pouch and roll	Predicate Devices: SIGMA sterilization pouch and roll (K180661)	Comparison
Performance Testing				
Sterilant Penetration	**Half-Cycle Efficacy**	The test meet the requirement of SAL 10^{-6}	The test meet the requirement of SAL 10^{-6}	Same
	Full-Cycle Efficacy	The test meet the requirement of SAL 10^{-6}	NA	The proposed device performs Sterilant Penetration of Full-Cycle Efficacy.
	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
Package Integrity (Physical Properties)	**Thickness Variations (mm)** *ASTM F 2251*	Passed	Passed	Same
	Tensile strength of plastic film * (kgf/mm2) *ASTM D882*	Passed	Passed	Same
	Tensile strength of paper* (N/15mm) *ISO 1924-2*	Passed	Passed	Same
	Air permeance of paper* (lb/in) *ISO 5636-3*	Passed	Passed	Same
	Thickness Variation (mm) *ASTM F2251*	Passed	Passed	Same
	Tear Resistance Test (kgf/cm2) *ASTM D 1004*	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 (g/15mm) *ASTM F88/F88M ; ISO 11607-1*	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
	Durability: Accelerated Aging Test *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	3 Years	3 Years	Same
Shelf Life	**Chemical Indicator (CI) Functionality**	3 Years	3 Years	Same
	Accelerated aging test (Seal Strength)	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 SIGMA sterilization pouch and roll have identical intended use and indication for use as the predicate devices. The subject device was compared to the predicate device by testing the Sterilant Penetration, Drying Time, Aeration, Biocompatibility, Package Integrity, Material Compatibility, Sterility Maintenance, and Chemical Indicator Efficacy.

The results of the SIGMA 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 Within 72 hours	EO = 2mg (Average) ECH = 0.3 mg Within 72 hours	Pass
Biocompatibility testing	ISO 10993-10 Third Edition 2010-08-01, "Biological Evaluation of Medical Devices- Part 10: Tests for irritation and skin sensitization".	Response Category: Negligible	Negligible (negative reaction)	Pass
Package Integrity/ Material Compatibility/ Sterility Maintenance	ANSI/AAMI/ISO 11607-1:2006/(R)2010/A1:2014, "Packaging for terminally sterilized medical devices- Part 1: Requirements for materials, sterile barrier systems and packaging systems"			
	ASTM D882-12, "Standard Test Method for Tensile Properties of Thin Plastic Sheeting"	CD > 400 MD > 450 *(kgf/mm^2)*	CD = 458 MD =462 *Note: the data is the min. value of test results after Steam Sterilization.*	Pass
	ASTM D 1004 -13, "Standard Test Method for Tear Resistance (Graves Tear) of Plastic Film and Sheeting"	CD > 300 MD > 350 *(kgf/mm^2)*	CD = 443 MD =453 *Note: the data is the min. value of test results after Steam Sterilization.*	Pass
	ASTM F 2251-13, "Standard Test Method for Thickness Measurement of Flexible Packaging Material"	±0.02	±0.003	Pass
	ASTM F1140/F1140M-13, "Standard Test Methods for Internal Pressurization Failure Resistance of Unrestrained Packages";	It pressurize to the 80% of the burst value and hold for 30s. Burst value > 5.0 (kPa)	Average Burst pressure = 5.8 (kPa) *Note: the data is after Accelerated Aging.*	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 Channels identified on package	Pass
	ASTM F88/F88M-15, "Standard Test Method for Seal Strength of Flexible Barrier Materials"	The strength > 356 (gf /25.4mm)	Site 1= 588 Site 2= 598 Site 3= 909 Site 4= 1016 *Note: the min. value of test results.*	Pass
	ASTM F 1980-07, "Standard Guide for Accelerated Aging of Sterile Barrier Systems for Medical Devices";	Incubated for 22.5 days under controlled conditions (Temp: 55°C / RH: 50%) simulating the real time for post-steam sterilization (135°C/15min) storage of 6 months.	a. Test articles (no product included and steam sterilized 135°C/15min) were accelerated aged at 55°C and 50% R.H to simulate the real time aging of 6 months. b. Test articles (product included and steam sterilized 135°C/15min) were accelerated aged at 55°C and 50% R.H to simulate the real time aging 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 F 1980-07, "Standard Guide for Accelerated Aging of Sterile Barrier Systems for Medical Devices";	Incubated for 137 days under controlled conditions (Temp: 55℃ / RH: 50%) simulating the real time for post-EO gas sterilization storage of 3 years.	a. Test articles (no product included) were accelerated aged at 55℃ and 50% R.H to simulate the real time aging of 3 years. b. Test articles (product included and EO sterilized) were accelerated aged at 55℃ and 50% R.H to simulate the real time aging of 3 years.	Pass
		Incubated for 137 days under controlled conditions (Temp: 55℃ / RH: 50%) simulating the real time storage of 3 years.	a. Test articles (no product included) were accelerated aged at 55℃,and 75% RH to simulate the real time aging of 3 years. b. Test articles (product included) were accelerated aged at 55℃,and 75% RH to simulate the real time aging of 3 years.	Pass
	ASTM D3078-02(R2013), "Standard Test Method For Determination Of Leaks In Flexible Packaging By Bubble Emission"	No Leakage	No Leakage	Pass
	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 < 1	CFU < 1	Pass
	ASTM F 1608, "Standard Test Method for Microbial Ranking of Porous Packaging Materials (Exposure Chamber Method)"	LRV > 1.7	Average LRV =3.31	Pass
Chemical Indicator Efficacy testing (Type 1 Process Indicators)	AAMI/ANSI/ISO 11140-1:2014 "Sterilization of Health Care Products-Chemical Indicators-Part 1: General Requirements"	**Steam** **Change color** 121℃ / 3.0 min & 134℃/ 0.5 min: Unacceptable result 121℃/10.0 min & 134℃/ 2.0 min: Acceptable result Dry heat 140℃/30 min: Unacceptable result	121℃ / 3.0 min & 134℃/ 0.5 min: the result of color is Blue 121℃/10.0 min & 134℃/ 2.0 min: the result of color is from Blue to Greenish Black Dry heat 140℃/30 min: the result of color is Blue.	Pass
	Change color in the presence of the sterilant (After steam sterilization cycles. The color of Chemical Indicator changes from Blue to Greenish Black; After EO sterilization cycles. The color of Chemical Indicator changes from Red to Yellow.)	**EO gas** **Change color** Absence of EO gas / 90 min: Unacceptable result EO gas Teat / 2 min : Unacceptable result EO gas Teat /20 min: Acceptable result	Absence of EO gas / 90 min: the result of color is Red. EO gas Teat / 2 min: the result of color is Red. EO gas Teat /20 min: the result of color is Yellow.	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 October 15, 2007 to December 15, 2010 that demonstrates: the test group which exposed to Steam maintain the color of Dark Green, the test group which exposed to EO maintain the color of Yellow, and the Control group maintain the original color from October 15, 2007, to December 15, 2010.	Pass

CONCLUSION

The conclusions drawn from the nonclinical tests demonstrate that SIGMA Sterilization Pouch and Roll is as safe, as effective, and performs as well as or better than the predicate K180661.