



June 5, 2018

Sigma Medical Supplies Corp.
% 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: K180661

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: February 27, 2018
Received: March 14, 2018

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. 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); good

manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); 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 <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (<https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/>) and CDRH Learn (<http://www.fda.gov/Training/CDRHLearn>). 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 (<http://www.fda.gov/DICE>) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Geeta K.
Pamidimukkala -S

for Tina Kiang, Ph.D.
Acting Director
Division of Anesthesiology,
General Hospital, Respiratory,
Infection Control, and Dental Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known)
K180661

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 steam auto claves and via Ethylene Oxide (EO). The recommended steam sterilization cycle parameters are 30 minutes at 121°C. The recommended EO sterilization cycle is 4 hours at 55°C with a relative humidity between 50%-85% and a sterilant concentration of 600 mg/L. Furthermore, the sterilization pouch and roll 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 5 types:

- Self-sealing sterilization 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.

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The defining characteristics of the 5 types 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.
- **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 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. Recommended Sterilization Load

Type	Dimension in S.I.	*Content / Max Load (lbs)
Self-Sealing Sterilization Pouches	57 mm × 133 mm	Metal 0.02
Self-Sealing Sterilization Pouches	70 mm × 257 mm	Plastic 0.01
Self-Sealing Sterilization Pouches	90 mm × 162 mm	Linens and Gauze 0.01
Self-Sealing Sterilization Pouches	90 mm × 168 mm	
Self-Sealing Sterilization Pouches	70 mm × 257mm	
Self-Sealing Sterilization Pouches	90 mm × 257 mm	
Self-Sealing Sterilization Pouches	90 mm × 265 mm	
Self-Sealing Sterilization Pouches	90 mm × 594 mm	
Self-Sealing Sterilization Pouches	133 mm × 289 mm	Metal 0.23
Self-Sealing Sterilization Pouches	133 mm × 391 mm	Plastic 0.27
Self-Sealing Sterilization Pouches	135 mm × 193 mm	Linens and Gauze 0.10
Self-Sealing Sterilization Pouches	135 mm × 283 mm	
Self-Sealing Sterilization Pouches	135 mm × 335 mm	
Self-Sealing Sterilization Pouches	150 mm × 610 mm	
Self-Sealing Sterilization Pouches	190 mm × 358 mm	
Self-Sealing Sterilization Pouches	190 mm × 365 mm	
Self-Sealing Sterilization Pouches	200 mm × 435 mm	
Self-Sealing Sterilization Pouches	300 mm × 380 mm	
Self-Sealing Sterilization Pouches	300 mm × 474 mm	
Self-Sealing Sterilization Pouches	300 mm × 485 mm	
Self-Sealing Sterilization Pouches	303 mm × 474 mm	Linens and Gauze 1.00
Self-Sealing Sterilization Pouches	305 mm × 416 mm	
Self-Sealing Sterilization Pouches	356 mm × 483 mm	Metal 1.31 Plastic 3.38 Linens and Gauze 1.16
Self-Sealing Sterilization Pouches	380 mm × 635 mm	Metal 1.48 Plastic 4.42 Linens and Gauze 1.51
Self-Sealing Sterilization Pouches	460 mm × 610 mm	Metal 1.79 Plastic 5.34 Linens and Gauze 1.82

Table 1. (Continued) Recommended Sterilization Load

Type	Dimension in S.I.	*Content / Max Load (lbs)
Sterilization Pouches, Flat	75 mm × 150 mm	Metal 0.13
Sterilization Pouches, Flat	75 mm × 200 mm	Plastic 0.02
Sterilization Pouches, Flat	75 mm × 300 mm	Linens and Gauze 0.02
Sterilization Pouches, Flat	100 mm × 200 mm	
Sterilization Pouches, Flat	100 mm × 300 mm	
Sterilization Pouches, Flat	100 mm × 550 mm	
Sterilization Pouches, Flat	120 mm × 250 mm	
Sterilization Pouches, Flat	120 mm × 280 mm	
Sterilization Pouches, Flat	150 mm × 200 mm	
Sterilization Pouches, Flat	150 mm × 250 mm	
Sterilization Pouches, Flat	150 mm × 300 mm	
Sterilization Pouches, Flat	150 mm × 380 mm	
Sterilization Pouches, Flat	150 mm × 550 mm	Metal 0.23 Plastic 0.03 Linens and Gauze 0.03
Sterilization Pouches, Flat	180 mm × 300 mm	Metal 0.13 Plastic 0.02
Sterilization Pouches, Flat	200 mm × 330 mm	Linens and Gauze 0.02
Sterilization Pouches, Flat	200 mm × 400 mm	Metal 0.86 Plastic 1.13 Linens and Gauze 0.51
Sterilization Pouches, Flat	200 mm × 600 mm	Metal 1.29 Plastic 1.69 Linens and Gauze 0.76
Sterilization Pouches, Flat	205 mm × 400 mm	Metal 0.86
Sterilization Pouches, Flat	250 mm × 300 mm	Plastic 1.13
Sterilization Pouches, Flat	250 mm × 450 mm	Linens and Gauze 0.51
Sterilization Pouches, Flat	300 mm × 380 mm	Metal 0.75
Sterilization Pouches, Flat	300 mm × 460 mm	Plastic 3.28
Sterilization Pouches, Flat	300 mm × 500 mm	Linens and Gauze 1.61
Sterilization Pouches, Flat	420 mm × 400 mm	
Sterilization Pouches, Flat	420 mm × 600 mm	Metal 1.12 Plastic 4.92 Linens and Gauze 2.41
Sterilization Pouches, Gusseted	100 mm × 40 mm × 300 mm	Metal 0.21 Plastic 0.05
Sterilization Pouches, Gusseted	150 mm × 50 mm × 400 mm	Linens and Gauze 0.08
Sterilization Pouches, Gusseted	200 mm × 50 mm × 400 mm	Metal 0.87 Plastic 1.68
Sterilization Pouches, Gusseted	250 mm × 60 mm × 480 mm	Linens and Gauze 0.90
Sterilization Pouches, Gusseted	300 mm × 70 mm × 500 mm	Metal 1.45 Plastic 3.78 Linens and Gauze 1.82

Table 1. (Continued) Recommended Sterilization Load

Type	Dimension in S.I.	*Content / Max Load (lbs)
Sterilization Rolls, Flat	50 mm × 200 M	Metal 0.02 Plastic 0.01 Linens and Gauze 0.01
Sterilization Rolls, Flat	50.8 mm × 200 M	
Sterilization Rolls, Flat	75 mm × 200 M	
Sterilization Rolls, Flat	76.2 mm × 200 M	
Sterilization Rolls, Flat	100 mm × 200 M	
Sterilization Rolls, Flat	101.6 mm × 200 M	
Sterilization Rolls, Flat	150 mm × 200 M	
Sterilization Rolls, Flat	152.4 mm × 200 M	
Sterilization Rolls, Flat	200 mm × 200 M	Metal 0.86 Plastic 1.13 Linens and Gauze 0.51
Sterilization Rolls, Flat	203.2 mm × 200 M	
Sterilization Rolls, Flat	250 mm × 200 M	
Sterilization Rolls, Flat	254 mm × 200 M	
Sterilization Rolls, Flat	300 mm × 200 M	
Sterilization Rolls, Flat	304.8 mm × 200 M	
Sterilization Rolls, Flat	350 mm × 200 M	
Sterilization Rolls, Flat	400 mm × 200 M	Metal 6.24 Plastic 2.99 Linens and Gauze 2.94
Sterilization Rolls, Flat	50.8 mm × 30.5 M	Metal 0.02 Plastic 0.01 Linens and Gauze 0.01
Sterilization Rolls, Flat	76.2 mm × 30.5 M	
Sterilization Rolls, Flat	101.6 mm × 30.5 M	
Sterilization Rolls, Flat	152.4 mm × 30.5 M	
Sterilization Rolls, Flat	203.2 mm × 30.5 M	Metal 0.86 Plastic 1.13 Linens and Gauze 0.51
Sterilization Rolls, Flat	254 mm × 30.5 M	
Sterilization Rolls, Gusseted	75 mm × 35 mm × 100 M	Metal 0.12 Plastic 0.02 Linens and Gauze 0.03
Sterilization Rolls, Gusseted	100 mm × 40 mm × 100M	
Sterilization Rolls, Gusseted	150 mm × 50 mm × 100 M	
Sterilization Rolls, Gusseted	200 mm × 50 mm × 100 M	Metal 0.87 Plastic 1.68 Linens and Gauze 0.90
Sterilization Rolls, Gusseted	250 mm × 60 mm × 100 M	
Sterilization Rolls, Gusseted	300 mm × 70 mm × 100 M	
Sterilization Rolls, Gusseted	350 mm × 80 mm × 100 M	
Sterilization Rolls, Gusseted	400 mm × 80 mm × 100 M	Metal 3.67 Plastic 3.00 Linens and Gauze 3.44

*Content:

1. Metal: For example, scalpels, clips, pins, forceps and trays. 2. Plastic: For example, infusion tubes, syringes, foley tubes and gloves, etc. 3. Linens and Cotton: For example, linens, drapes, towels, gauze, and cotton wool, etc.

K180661 510(k) Summary

1 Summitter'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: Mason Huang
Regulatory Affair Specialist
886-4-24366111 ext. 127
E-mail: mason@sigma-medical.com.tw
Or
Jack Wang
President /C.E.O
Date Prepared: May 30, 2018

2 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

3 Predicate Devices

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

Manufacturer : SIGMA Medical Supplies Corp.

Product Code : 1) FRG 2) JOJ

510(k) number : K102158

4 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 steam auto claves and via Ethylene Oxide (EO). The recommended steam sterilization cycle parameters are 30 minutes at 121°C. The recommended EO sterilization cycle is 4 hours at 55°C with a relative humidity between 50%-85% and a sterilant concentration of 600 mg/L. Furthermore, the sterilization pouch and roll 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 5 types:

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

The defining characteristics of the 5 types 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.
- **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 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)
Self-Sealing Sterilization Pouches	SMSE057133	57 mm × 133 mm	Metal 0.02
	SMSE070257	70 mm × 257 mm	Plastic 0.01
	SMSE090162	90 mm × 162 mm	Lines and Gauze 0.01
	SMSE090168	90 mm × 168 mm	
	SMSE070257	70 mm × 257mm	
	SMSE090257	90 mm × 257 mm	
	SMSE090265	90 mm × 265 mm	
	SMSE090594	90 mm × 594 mm	Metal 0.23
	SMSE133289	133 mm × 289 mm	Plastic 0.27
	SMSE133391	133 mm × 391 mm	Lines and Gauze 0.10
	SMSE135193	135 mm × 193 mm	
	SMSE135283	135 mm × 283 mm	
	SMSE180335	135 mm × 335 mm	
	SMSE150610	150 mm × 610 mm	
	SMSE190358	190 mm × 358 mm	
	SMSE190365	190 mm × 365 mm	
	SMSE200435	200 mm × 435 mm	
	SMSE300380	300 mm × 380 mm	
	SMSE300474	300 mm × 474 mm	Metal 1.13
	SMSE300485	300 mm × 485 mm	Plastic 2.92
	SMSE303474	303 mm × 474 mm	Lines and Gauze 1.00
	SMSE305416	305 mm × 416 mm	
	SMSE356483	356 mm × 483 mm	Metal 1.31 Plastic 3.38 Linens and Gauze 1.16
	SMSE380635	380 mm × 635 mm	Metal 1.48 Plastic 4.42 Lines and Gauze 1.51
	SMSE460610	460 mm × 610 mm	Metal 1.79 Plastic 5.34 Lines and Gauze 1.82

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)
Sterilization Pouches, Flat	SMFP075150	75 mm × 150 mm	Metal 0.13
	SMFP075200	75 mm × 200 mm	Plastic 0.02
	SMFP075300	75 mm × 300 mm	Linens and Gauze 0.02
	SMFP100200	100 mm × 200 mm	
	SMFP100300	100 mm × 300 mm	
	SMFP100550	100 mm × 550 mm	
	SMFP120250	120 mm × 250 mm	
	SMFP120280	120 mm × 280 mm	
	SMFP150200	150 mm × 200 mm	
	SMFP150250	150 mm × 250 mm	
	SMFP150300	150 mm × 300 mm	
	SMFP150380	150 mm × 380 mm	
	SMFP150550	150 mm × 550 mm	Metal 0.23 Plastic 0.03 Linens and Gauze 0.03
	SMFP180300	180 mm × 300 mm	Metal 0.13 Plastic 0.02
	SMFP200330	200 mm × 330 mm	Linens and Gauze 0.02
	SMFP200400	200 mm × 400 mm	Metal 0.86 Plastic 1.13 Linens and Gauze 0.51
	SMFP200600	200 mm × 600 mm	Metal 1.29 Plastic 1.69 Linens and Gauze 0.76
	SMFP205400	205 mm × 400 mm	Metal 0.86
	SMFP250300	250 mm × 300 mm	Plastic 1.13
	SMFP250450	250 mm × 450 mm	Linens and Gauze 0.51
	SMFP300380	300 mm × 380 mm	Metal 0.75
	SMFP300460	300 mm × 460 mm	Plastic 3.28
	SMFP300500	300 mm × 500 mm	Linens and Gauze 1.61
	SMFP420400	420 mm × 400 mm	
	SMFP420600	420 mm × 600 mm	Metal 1.12 Plastic 4.92 Linens and Gauze 2.41
Sterilization Pouches, Gusseted	SMGP100300	100 mm × 40 mm × 300 mm	Metal 0.21 Plastic 0.05
	SMGP150400	150 mm × 50 mm × 400 mm	Linens and Gauze 0.08
	SMGP200400	200 mm × 50 mm × 400 mm	Metal 0.87 Plastic 1.68
	SMGP250480	250 mm × 60 mm × 480 mm	Linens and Gauze 0.90
	SMGP300500	300 mm × 70 mm × 500 mm	Metal 1.45 Plastic 3.78 Linens and Gauze 1.82

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)
Sterilization Rolls, Flat	SMFR 022	50 mm × 200 M	Metal 0.02 Plastic 0.01 Linens and Gauze 0.01
	SMFR 902	50.8 mm × 200 M	
	SMFR 032	75 mm × 200 M	
	SMFR 912	76.2 mm × 200 M	
	SMFR 042	100 mm × 200 M	
	SMFR 922	101.6 mm × 200 M	
	SMFR 062	150 mm × 200 M	
	SMFR 932	152.4 mm × 200 M	
	SMFR 082	200 mm × 200 M	Metal 0.86 Plastic 1.13 Linens and Gauze 0.51
	SMFR 942	203.2 mm × 200 M	
	SMFR 102	250 mm × 200 M	
	SMFR 952	254 mm × 200 M	
	SMFR 122	300 mm × 200 M	
	SMFR 962	304.8 mm × 200 M	
	SMFR 142	350 mm × 200 M	
	SMFR 162	400 mm × 200 M	Metal 6.24 Plastic 2.99 Linens and Gauze 2.94
	SMFR 02-1	50.8 mm × 30.5 M	Metal 0.02 Plastic 0.01 Linens and Gauze 0.01
	SMFR 03-1	76.2 mm × 30.5 M	
	SMFR 04-1	101.6 mm × 30.5 M	
	SMFR 06-1	152.4 mm × 30.5 M	
	SMFR 08-1	203.2 mm × 30.5 M	Metal 0.86 Plastic 1.13 Linens and Gauze 0.51
	SMFR 10-1	254 mm × 30.5 M	
Sterilization Rolls, Gusseted	SMGR 031	75 mm × 35 mm × 100 M	Metal 0.12 Plastic 0.02 Linens and Gauze 0.03
	SMGR 041	100 mm × 40 mm × 100M	
	SMGR 061	150 mm × 50 mm × 100 M	
	SMGR 081	200 mm × 50 mm × 100 M	Metal 0.87 Plastic 1.68 Linens and Gauze 0.90
	SMGR 101	250 mm × 60 mm × 100 M	
	SMGR 121	300 mm × 70 mm × 100 M	
	SMGR 141	350 mm × 80 mm × 100 M	Metal 3.67 Plastic 3.00 Linens and Gauze 3.44
	SMGR 161	400 mm × 80 mm × 100 M	

*Content:

1. Metal: For example, scalpels, clips, pins, forceps and trays. 2. Plastic: For example, infusion tubes, syringes, foley tubes and gloves, etc. 3. Linens and Cotton: For example, linens, drapes, towels, gauze, and cotton wool, etc.

5 Device Description

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°C. The recommended EO sterilization cycle is 4 hours at 55°C with a relative humidity between 50%-85% and a sterilant concentration of 600 mg/L. The medical devices 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 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.

6 Technological Characteristic 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	SIGMA sterilization pouch and roll	SIGMA sterilization pouch and roll (K102158)																																																																													
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 sterilization pouch and roll are intended to provide health care workers with an effective method to enclose devices intended for sterilization in steam autolaves and via Ethylene Oxide (EO). The recommended steam sterilization cycle parameters are 30 minutes at 121°C. The recommended EO sterilization cycle is 4 hours at 55°C with a relative humidity between 50%-85% and a sterilant concentration of 600 mg/L. Furthermore, the sterilization pouch and roll 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 autolaves and via Ethylene Oxide (EO). The recommended steam sterilization cycle parameters are 30 minutes at 121°C. The recommended EO sterilization cycle is 4 hours at 55°C with a relative humidity between 50%-85% and a sterilant concentration of 600 mg/L. Furthermore, the sterilization pouch and roll 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 maintenance of sterility is different. The proposed device maintains the enclosed devices up until 3 years post EO gas sterilization and maintains the enclosed devices up until 6 months post Steam sterilization.																																																																												
Pouch Types	- Self-sealing sterilization pouches - Sterilization pouches, Flat - Sterilization pouches, Gusseted - Sterilization rolls, Flat - Sterilization rolls, Gusseted	- Self-sealing sterilization pouches - Sterilization pouches, Flat - Sterilization pouches, Gusseted - Sterilization rolls, Flat - Sterilization rolls, Gusseted	Same																																																																												
Device models (Configurations/Dimensions)	<table><tr><th colspan="2">Self-Sealing Sterilization Pouches</th></tr><tr><th>Model</th><th>Dimension (mm)</th></tr><tr><td>SMSE057133</td><td>57 mm × 133 mm</td></tr><tr><td>SMSE070257</td><td>70 mm × 257 mm</td></tr><tr><td>SMSE090162</td><td>90 mm × 162 mm</td></tr><tr><td>SMSE090168</td><td>90 mm × 168 mm</td></tr><tr><td>SMSE070257</td><td>70 mm × 257mm</td></tr><tr><td>SMSE090257</td><td>90 mm × 257 mm</td></tr><tr><td>SMSE090265</td><td>90 mm × 265 mm</td></tr><tr><td>SMSE090594</td><td>90 mm × 594 mm</td></tr><tr><td>SMSE133289</td><td>133 mm × 289 mm</td></tr><tr><td>SMSE133391</td><td>133 mm × 391 mm</td></tr><tr><td>SMSE135193</td><td>135 mm × 193 mm</td></tr><tr><td>SMSE135283</td><td>135 mm × 283 mm</td></tr><tr><td>SMSE180335</td><td>135 mm × 335 mm</td></tr><tr><td>SMSE150610</td><td>150 mm × 610 mm</td></tr><tr><td>SMSE190358</td><td>190 mm × 358 mm</td></tr><tr><td>SMSE190365</td><td>190 mm × 365 mm</td></tr><tr><td>SMSE200435</td><td>200 mm × 435 mm</td></tr><tr><td>SMSE300380</td><td>300 mm × 380 mm</td></tr><tr><td>SMSE300474</td><td>300 mm × 474 mm</td></tr><tr><td>SMSE300485</td><td>300 mm × 485 mm</td></tr><tr><td>SMSE303474</td><td>303 mm × 474 mm</td></tr><tr><td>SMSE305416</td><td>305 mm × 416 mm</td></tr><tr><td>SMSE356483</td><td>356 mm × 483 mm</td></tr><tr><td>SMSE380635</td><td>380 mm × 635 mm</td></tr><tr><td>SMSE460610</td><td>460 mm × 610 mm</td></tr></table>	Self-Sealing Sterilization Pouches		Model	Dimension (mm)	SMSE057133	57 mm × 133 mm	SMSE070257	70 mm × 257 mm	SMSE090162	90 mm × 162 mm	SMSE090168	90 mm × 168 mm	SMSE070257	70 mm × 257mm	SMSE090257	90 mm × 257 mm	SMSE090265	90 mm × 265 mm	SMSE090594	90 mm × 594 mm	SMSE133289	133 mm × 289 mm	SMSE133391	133 mm × 391 mm	SMSE135193	135 mm × 193 mm	SMSE135283	135 mm × 283 mm	SMSE180335	135 mm × 335 mm	SMSE150610	150 mm × 610 mm	SMSE190358	190 mm × 358 mm	SMSE190365	190 mm × 365 mm	SMSE200435	200 mm × 435 mm	SMSE300380	300 mm × 380 mm	SMSE300474	300 mm × 474 mm	SMSE300485	300 mm × 485 mm	SMSE303474	303 mm × 474 mm	SMSE305416	305 mm × 416 mm	SMSE356483	356 mm × 483 mm	SMSE380635	380 mm × 635 mm	SMSE460610	460 mm × 610 mm	<table><tr><th colspan="2">Self-Sealing Sterilization Pouches</th></tr><tr><th>Model</th><th>Dimension (mm)</th></tr><tr><td>SMSE057133</td><td>57 mm × 133 mm</td></tr><tr><td>SMSE090162</td><td>90 mm × 162 mm</td></tr><tr><td>SMSE070257</td><td>70 mm × 257mm</td></tr><tr><td>SMSE090257</td><td>90 mm × 257 mm</td></tr><tr><td>SMSE135283</td><td>135 mm × 283 mm</td></tr><tr><td>SMSE180335</td><td>135 mm × 335 mm</td></tr><tr><td>SMSE190358</td><td>190 mm × 358 mm</td></tr><tr><td>SMSE300380</td><td>300 mm × 380 mm</td></tr><tr><td>SMSE300474</td><td>300 mm × 474 mm</td></tr></table>	Self-Sealing Sterilization Pouches		Model	Dimension (mm)	SMSE057133	57 mm × 133 mm	SMSE090162	90 mm × 162 mm	SMSE070257	70 mm × 257mm	SMSE090257	90 mm × 257 mm	SMSE135283	135 mm × 283 mm	SMSE180335	135 mm × 335 mm	SMSE190358	190 mm × 358 mm	SMSE300380	300 mm × 380 mm	SMSE300474	300 mm × 474 mm	The models (dimensions) of type "Self-Sealing Sterilization Pouches" are different. There are 16 additional models in Proposed device. The additional models (Type, Model and Dimension) of Proposed device are shown in Table 3.
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K180661 510(K) SUMMARY

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

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Device models (Configurations/Dimensions)	<table><tr><th colspan="2">Sterilization Pouches, Flat</th></tr><tr><th>Model</th><th>Dimension (mm)</th></tr><tr><td>SMFP075150</td><td>75 mm × 150 mm</td></tr><tr><td>SMFP075200</td><td>75 mm × 200 mm</td></tr><tr><td>SMFP075300</td><td>75 mm × 300 mm</td></tr><tr><td>SMFP100200</td><td>100 mm × 200 mm</td></tr><tr><td>SMFP100300</td><td>100 mm × 300 mm</td></tr><tr><td>SMFP100550</td><td>100 mm × 550 mm</td></tr><tr><td>SMFP120250</td><td>120 mm × 250 mm</td></tr><tr><td>SMFP120280</td><td>120 mm × 280 mm</td></tr><tr><td>SMFP150200</td><td>150 mm × 200 mm</td></tr><tr><td>SMFP150250</td><td>150 mm × 250 mm</td></tr><tr><td>SMFP150300</td><td>150 mm × 300 mm</td></tr><tr><td>SMFP150380</td><td>150 mm × 380 mm</td></tr><tr><td>SMFP150550</td><td>150 mm × 550 mm</td></tr><tr><td>SMFP180300</td><td>180 mm × 300 mm</td></tr><tr><td>SMFP200330</td><td>200 mm × 330 mm</td></tr><tr><td>SMFP200400</td><td>200 mm × 400 mm</td></tr><tr><td>SMFP200600</td><td>200 mm × 600 mm</td></tr><tr><td>SMFP205400</td><td>205 mm × 400 mm</td></tr><tr><td>SMFP250300</td><td>250 mm × 300 mm</td></tr><tr><td>SMFP250450</td><td>250 mm × 450 mm</td></tr><tr><td>SMFP300380</td><td>300 mm × 380 mm</td></tr><tr><td>SMFP300460</td><td>300 mm × 460 mm</td></tr><tr><td>SMFP300500</td><td>300 mm × 500 mm</td></tr><tr><td>SMFP420400</td><td>420 mm × 400 mm</td></tr><tr><td>SMFP420600</td><td>420 mm × 600 mm</td></tr></table>	Sterilization Pouches, Flat		Model	Dimension (mm)	SMFP075150	75 mm × 150 mm	SMFP075200	75 mm × 200 mm	SMFP075300	75 mm × 300 mm	SMFP100200	100 mm × 200 mm	SMFP100300	100 mm × 300 mm	SMFP100550	100 mm × 550 mm	SMFP120250	120 mm × 250 mm	SMFP120280	120 mm × 280 mm	SMFP150200	150 mm × 200 mm	SMFP150250	150 mm × 250 mm	SMFP150300	150 mm × 300 mm	SMFP150380	150 mm × 380 mm	SMFP150550	150 mm × 550 mm	SMFP180300	180 mm × 300 mm	SMFP200330	200 mm × 330 mm	SMFP200400	200 mm × 400 mm	SMFP200600	200 mm × 600 mm	SMFP205400	205 mm × 400 mm	SMFP250300	250 mm × 300 mm	SMFP250450	250 mm × 450 mm	SMFP300380	300 mm × 380 mm	SMFP300460	300 mm × 460 mm	SMFP300500	300 mm × 500 mm	SMFP420400	420 mm × 400 mm	SMFP420600	420 mm × 600 mm	<table><tr><th colspan="2">Sterilization Pouches, Flat</th></tr><tr><th>Model</th><th>Dimension (mm)</th></tr><tr><td>SMFP075200</td><td>75 mm × 200 mm</td></tr><tr><td>SMFP075300</td><td>75 mm × 300 mm</td></tr><tr><td>SMFP100200</td><td>100 mm × 200 mm</td></tr><tr><td>SMFP100300</td><td>100 mm × 300 mm</td></tr><tr><td>SMFP150300</td><td>150 mm × 300 mm</td></tr><tr><td>SMFP200400</td><td>200 mm × 400 mm</td></tr><tr><td>SMFP250450</td><td>250 mm × 450 mm</td></tr><tr><td>SMFP300500</td><td>300 mm × 500 mm</td></tr></table>	Sterilization Pouches, Flat		Model	Dimension (mm)	SMFP075200	75 mm × 200 mm	SMFP075300	75 mm × 300 mm	SMFP100200	100 mm × 200 mm	SMFP100300	100 mm × 300 mm	SMFP150300	150 mm × 300 mm	SMFP200400	200 mm × 400 mm	SMFP250450	250 mm × 450 mm	SMFP300500	300 mm × 500 mm	The models (dimensions) of type "Sterilization Pouches, Flat" are different. There are 17 additional models in Proposed device. The additional models (Type, Model and Dimension) of Proposed device are shown in Table 3.
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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 (K102158)	Comparison
Steam Sterilization cycle	The recommended steam sterilization cycle parameters are 30 minutes at 121°C.	The recommended steam sterilization cycle parameters are 30 minutes at 121°C.	Same
EO gas Sterilization cycle	The recommended EO sterilization cycle is 4 hours at 55°C with a relative humidity between 50%-85% and a sterilant concentration of 600 mg/L.	The recommended EO sterilization cycle is 4 hours at 55°C with a relative humidity between 50%-85% and a sterilant concentration of 600 mg/L.	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. 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.	Same
Steam Chemical Indicator 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 Chemical Indicator 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

K180661 510(K) SUMMARY

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 (K102158)	Compar- ison
Performance Testing				
Sterilant Penetration	Half-Cycle Efficacy	The test meet the require- ment of SAL 10^{-6}	The test meet the require- ment of SAL 10^{-6}	Same
	Chemical Indicator (CI) Func- tionality and Endpoint	The sterilant penetrated through the pouch configu- ration and affected the CI color change to the end- point color	The sterilant penetrated through the pouch configu- ration and affected the CI color change to the end- point color	Same
Package Integrity (Physical Properties)	Thickness Variations (mm) <i>ASTM F 2251</i>	Passed	Passed	Same
	Tensile strength of plastic film * (kgf/mm2) <i>ASTM D882</i>	Passed	Passed	Same
	Tensile strength of paper* (N/15mm) <i>ISO 1924-2</i>	Passed	Passed	Same
	Air permeance of paper* (lb/in) <i>ISO 5636-3</i>	Passed	Passed	Same
	Thickness Variation (mm) <i>ASTM F2251</i>	Passed	Passed	Same
	Tear Resistance Test (kgf/cm2) <i>ASTM D 1004</i>	Passed	Passed	Same
	Burst Strength (kPa) <i>ASTM F1140 ; ISO 11607-1</i>	Passed	Passed	Same
	Bubble Leak Test <i>ASTM D 3078 ; ASTM-F 2096</i>	Passed	Passed	Same
	Seal Peel Test (g/15mm) <i>ASTM F88/F88M ; ISO 11607-1</i>	Passed	Passed	Same
	Dye penetration Test <i>ASTM F 1929 ;ISO 11607-1</i>	Passed	Passed	Same
	Microbial Barrier Test <i>DIN 58953-6 ;or ASTM F 1608</i>	Passed	Passed	Same
	Toxicological Properties (Biocompatibility Test) <i>ANSI/AAMI/ISO 10993-10</i>	Passed	Passed	Same
	Durability: Accelerated Aging Test <i>ASTM F 1980 ; ISO 11607-1</i>	Passed	Passed	Same
End Point / Post Pro- cessing Col- or 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 require-
ments.

Table 3 Additional models of SIGMA sterilization pouch and roll
(Type, Model and Dimension)

Type	Model	Dimension in S.I.
Self-Sealing Sterilization Pouches	SMSE070257	70 mm × 257 mm
	SMSE090168	90 mm × 168 mm
	SMSE090265	90 mm × 265 mm
	SMSE090594	90 mm × 594 mm
	SMSE133289	133 mm × 289 mm
	SMSE133391	133 mm × 391 mm
	SMSE135193	135 mm × 193 mm
	SMSE150610	150 mm × 610 mm
	SMSE190365	190 mm × 365 mm
	SMSE200435	200 mm × 435 mm
	SMSE300485	300 mm × 485 mm
	SMSE303474	303 mm × 474 mm
	SMSE305416	305 mm × 416 mm
	SMSE356483	356 mm × 483 mm
	SMSE380635	380 mm × 635 mm
	SMSE460610	460 mm × 610 mm
Sterilization Pouches, Flat	SMFP075150	75 mm × 150 mm
	SMFP100550	100 mm × 550 mm
	SMFP120250	120 mm × 250 mm
	SMFP120280	120 mm × 280 mm
	SMFP150200	150 mm × 200 mm
	SMFP150250	150 mm × 250 mm
	SMFP150380	150 mm × 380 mm
	SMFP150550	150 mm × 550 mm
	SMFP180300	180 mm × 300 mm
	SMFP200330	200 mm × 330 mm
	SMFP200600	200 mm × 600 mm
	SMFP205400	205 mm × 400 mm
	SMFP250300	250 mm × 300 mm
	SMFP300380	300 mm × 380 mm
	SMFP300460	300 mm × 460 mm
	SMFP420400	420 mm × 400 mm
	SMFP420600	420 mm × 600 mm
Sterilization Rolls, Flat	SMFR 902	50.8 mm × 200 M
	SMFR 912	76.2 mm × 200 M
	SMFR 922	101.6 mm × 200 M
	SMFR 932	152.4 mm × 200 M
	SMFR 942	203.2 mm × 200 M
	SMFR 952	254 mm × 200 M
	SMFR 962	304.8 mm × 200 M
	SMFR 02-1	50.8 mm × 30.5 M
	SMFR 03-1	76.2 mm × 30.5 M
	SMFR 04-1	101.6 mm × 30.5 M
	SMFR 06-1	152.4 mm × 30.5 M
	SMFR 08-1	203.2 mm × 30.5 M
	SMFR 10-1	254 mm × 30.5 M

7 Summary of Non-Clinical Testing

The SIGMA sterilization pouch and roll has the 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 follows:

- The Sterilant Penetration, Drying Time, Aeration, testing performed as described in AAMI / ANSI / ISO 17665-1:2006/(R)2013 and ISO TS 17665-2:2009 for steam sterilization as well as AAMI / ANSI / ISO 11135:2014 for EO. The testing results demonstrate the ability of the sterilant to penetrate the Sigma Sterilization Pouch and Roll.
- The Biocompatibility testing performed as described in ISO 10993-10:2010(E), ISO 10993-1:2009/Cor. 1:2010(E), ISO 10993-12:2012(E), and ISO/IEC 17025:2005. The testing results demonstrate the Sigma Sterilization Pouch and Roll showed “negative reaction”. And the SIGMA sterilization pouch and roll meets the requirements ISO 10993-10:2010(E). The EO sterilization residuals meets the requirements AAMI / ANSI / ISO 10993-7:2008 (R) 2012.
- The Package Integrity, Material Compatibility, Sterility Maintenance testing performed as described in AAMI / ANSI / ISO 11607-1:2006//A1:2014, “Packaging for terminally sterilized medical devices – Part 1: Requirements for materials, sterile barrier systems and packaging systems”; ASTM D882, “Standard Test Method for Tensile Properties of Thin Plastic Sheeting”; ASTM D 5035, “Standard Test Method for Breaking Force and Elongation of Textile Fabrics (Strip Method)”; ASTM F 2251-03, “Standard Test Method for Thickness Measurement of Flexible Packaging Material”; ASTM D 1922, “Standard Test Method for Propagation Tear Resistance of Plastic Film and Thin Sheeting by Pendulum Method”; ASTM F 1140-07, “Standard Test Methods for Internal Pressurization Failure Resistance of Unrestrained Packages”; ASTM F 1929-98 (04), “Standard Test Method for Detecting Seal Leaks in Porous Medical Packaging by Dye Penetration”; ASTM F88/F88M-09, “Standard Test Method for Seal Strength of Flexible Barrier Materials”; ASTM F 1980-2007, “Standard Guide for Accelerated Aging of Sterile Barrier Systems for Medical Devices”; DIN 58953-6:2010-05, “Sterilization - Sterile supply - Part 6: Microbial barrier testing of packaging materials for medical devices which are to be sterilized”. The testing results demonstrate the ability of the Sigma Sterilization Pouch and Roll to maintain the package integrity over the claimed shelf life.

The Chemical Indicator Efficacy testing performed as described in AAMI / ANSI / ISO 11140-1:2014 “Sterilization of Health Care Products – Chemical Indicators – Part 1: General Requirements”. There are two types of the Process Indicator ink printed on the SIGMA sterilization pouch and roll. The description of the two types ink as follows:
- Class 1 Process Indicators for STEAM

The testing demonstrates the ability of the Sigma Sterilization Pouch and Roll and its Class 1 Process Indicators for STEAM to remain stable before use based on its shelf life data, change color in the presence of the sterilant, and to maintain the endpoint stability of the color change after being in the presence of the sterilant. The STEAM Pro-

cess Indicators ink printed on the SIGMA sterilization pouch and roll meets the requirements ISO 11140-1:2014.

- Class 1 Process Indicators for EO gas

The testing demonstrates the ability of the Sigma Sterilization Pouch and Roll and its Class 1 Process Indicators for STEAM to remain stable before use based on its shelf life data, change color in the presence of the sterilant, and to maintain the endpoint stability of the color change after being in the presence of the sterilant. The EO gas Process Indicators ink printed on the SIGMA sterilization pouch and roll meets the requirements ISO 11140-1:2014.

8 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 K102158.