



June 6, 2018

Sigma Medical Supplies Corporation
% 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: K180672

Trade/Device Name: Sterilization Pouch/Roll Made with Tyvek
Regulation Number: 21 CFR 880.6850
Regulation Name: Sterilization Wrap
Regulatory Class: Class II
Product Code: FRG, JOJ
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)

K180672

Device Name

Sterilization Pouch/Roll Made with Tyvek®

Indications for Use (Describe)

The Sterilization Pouch/Roll Made with Tyvek® are intended to provide health care workers with an effective method to enclose devices intended for sterilization in the STERRAD® 100S Sterilizer. 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 sterilization.

The pouches and rolls are printed with a chemical indicator bar which is a process indicator (ISO 11140-1:2005) that changes from red to blue (or lighter) when exposed to hydrogen peroxide vapor during processing in the STERRAD® 100S Sterilizer.

The Sterilization Pouch/Roll Made with Tyvek® is offered in the follow 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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K180672 510(K) Summary

5.1 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: 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 23, 2018

5.2 **Device Trade Name:**

Trade Name: Sterilization Pouch/Roll Made with Tyvek®

Common/usual Name: Sterilization Pouch/Roll Made with Tyvek®

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

5.3 **Predicate Devices:**

The predicate device [510(k) Notification K133838, cleared March 11, 2015] is the Sterilization Pouch/Roll Made with Tyvek®
Manufacturer : SIGMA Medical Supplies Corp.
Product Code : 1) FRG 2) JOJ
510(k) number : K133838

5.4 Intended Use

The Sterilization Pouch/Roll Made with Tyvek® are intended to provide health care workers with an effective method to enclose devices intended for sterilization in the STERRAD® 100S Sterilizer. 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 sterilization.

The pouches and rolls are printed with a chemical indicator bar which is a process indicator (ISO 11140-1:2005) that changes from red to blue (or lighter) when exposed to hydrogen peroxide vapor during processing in the STERRAD® Sterilization System.

5.5 Device Description

Sterilization Pouch/Roll Made with Tyvek® is intended to be used to contain medical devices to be terminally sterilized in the STERRAD® 100S Sterilization System. The medical devices are inserted into the Pouch/Roll, sealed, and then sterilized in the STERRAD® 100S Sterilization System (The recommended cycle parameter is 6 minutes (Injection volume: 2880µL) at 50°C.). After completion of the sterilization process, the Pouch/Roll maintains 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 sterilization.

The Pouch/Roll is printed with a chemical indicator bar that changes from red to blue (or lighter) when exposed to hydrogen peroxide vapor during processing in the STERRAD® 100S Sterilization System.

The pouches are constructed from Tyvek®/plastic films, with H₂O₂ Chemical Indicator printed onto the Tyvek® film. 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 STERRAD® Sterilization Systems.

The H₂O₂ 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. H₂O₂ Chemical Indicators do not signify sterilization; they only indicate that the indicator has been exposed to the hydrogen peroxide. The color of the Chemical Indicator changes from red to blue (or lighter) when exposed to hydrogen peroxide.

The Sterilization Pouch/Roll Made with Tyvek® is offered in the follow 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 Tyvek® and used to seal the pouch. Release Tyvek® used in the pouch is a laminated sheet with composing structure of Tyvek®, PET, PE. It is a strip to cover the adhesive area and is released before seal the pouch. The Tyvek® conforms to recognized material standards and can be sterilized by Gas plasma in the STER-RAD® 100S Sterilization System's standard cycle. The Process Indicators Ink printed on the Tyvek® will exhibit a color change after the pouch is exposed to Gas plasma.
- **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 used.
- **Sterilization pouches, Gusseted:** These pouches are the same as the Sterilization pouches, flat, except that the plastic film is folded on both long 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 Tyvek® 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 Tyvek® are the same with the self-sealing sterilization pouches.
- **Sterilization rolls, Gusseted:** These rolls are the same as the flat sterilization roll, except that the plastic film is folded on both long sides instead of flat. This design is convenient to enclose the medical devices with certain height.

The following table (Table 5-1) lists the model numbers of the Sterilization Pouch/Roll Made with Tyvek® by type, model, dimensions, and max load (for pouches):

Table 5-1. The model numbers of Sterilization Pouch/Roll Made with Tyvek®
(Type, Model, Dimension, Max Load)

Type	Model	Dimensions (mm)	Content / Max Load (lbs)		
			Metal	Plastic	Linens and Gauze
Self-sealing Sterilization Pouches	TYSE057133	57mm×133mm	0.0354	0.0327	0.0141
	TYSE090162	90mm×162mm	0.0534	0.0495	0.0214
	TYSE090256	90 mm×256 mm	0.1218	0.1129	0.0734
	TYSE070257	70mm×257mm	0.0807	0.0748	0.0323
	TYSE090257	90mm×257mm	0.1218	0.1129	0.0734
	TYSE133282	133 mm×282 mm	0.2424	0.4144	0.1940
	TYSE135283	135mm×283mm	0.2424	0.4144	0.1940
	TYSE135335	135mm×335mm	0.2986	0.5548	0.2502
	TYSE190358	190mm×358mm	0.4809	1.0107	0.4325
	TYSE254408	254 mm×408 mm	0.7224	1.5303	0.6804
	TYSE300380	300mm×380mm	0.8488	1.9303	0.8004
	TYSE300474	300mm×474mm	1.0744	2.4943	1.0260
	TYSE305485	305 mm × 485 mm	1.0794	2.4995	1.0296
Sterilization Pouches, Flat	TYFP075200	75mm×200mm	0.0826	0.0347	0.017
	TYFP075300	75mm×300mm	0.1576	0.0662	0.032
	TYFP100200	100mm×200mm	0.1326	0.0557	0.027
	TYFP100300	100mm×300mm	0.2326	0.0977	0.0474
	TYFP150255	150 mm × 255 mm	0.2326	0.0977	0.0474
	TYFP150300	150mm×300mm	0.3826	0.3977	0.1974
	TYFP190330	190 mm × 330 mm	0.5836	0.9407	0.3654
	TYFP200400	200mm×400mm	0.7326	1.0977	0.5474
	TYFP250450	250mm×450mm	1.0576	1.7477	0.8724
	TYFP300500	300mm×500mm	1.4326	2.4977	1.2474
Sterilization Pouches, Gusseted	TYGP100300	100mm×40mm300mm	0.2592	0.0488	0.0146
	TYGP150400	150mm×50mmx400mm	0.5592	0.9488	0.2842
	TYGP200400	200mm×50mmx400mm	0.7592	1.5488	0.4842
	TYGP250480	250mm×60mmx480mm	1.1592	2.7488	0.8842
	TYGP300500	300mm×70mmx500mm	1.4592	3.6488	1.1842

Type	Model	Dimensions (mm)	Content / Max Load (lbs)		
			Metal	Plastic	Linens and Gauze
Sterilization Rolls, Flat	TYFR050070	50mm × 70M	0.0354	0.0327	0.0141
	TYFR022f	50.8 mm × 61 M	0.0354	0.0327	0.0141
	TYFR075070	75mm × 70M	0.0811	0.0342	0.016
	TYFR100070	100mm × 70M	0.1326	0.0557	0.027
	TYFR042f	101.6 mm × 61 M	0.1326	0.0557	0.027
	TYFR150070	150mm × 70M	0.2326	0.0977	0.0474
	TYFR062f	152.4 mm × 61 M	0.2326	0.0977	0.0474
	TYFR200070	200mm × 70M	0.7326	1.0977	0.5474
	TYFR082f	203.2 mm × 61 M	0.7326	1.0977	0.5474
	TYFR250070	250mm × 70M	1.0576	1.7477	0.8724
	TYFR102f	254 mm × 61 M	1.0576	1.7477	0.8724
	TYFR300070	300mm × 70M	1.4326	2.4977	1.2474
	TYFR350070	350mm × 70M	1.6326	2.7977	1.4474
	TYFR400070	400mm × 70M	1.8306	3.2931	1.6422
	TYFR450070	450mm × 70M	2.664	4.3655	2.1795
	TYFR500070	500mm × 70M	3.559	6.2162	3.0885
	TYFR050100	50mm × 100M	0.0354	0.0327	0.0141
	TYFR075100	75mm × 100M	0.0811	0.0342	0.016
	TYFR100100	100mm × 100M	0.1326	0.0557	0.027
	TYFR150100	150mm × 100M	0.2326	0.0977	0.0474
	TYFR200100	200mm × 100M	0.7326	1.0977	0.5474
	TYFR250100	250mm × 100M	1.0576	1.7477	0.8724
	TYFR300100	300mm × 100M	1.4326	2.4977	1.2474
	TYFR350100	350mm × 100M	1.6326	2.7977	1.4474
	TYFR400100	400mm × 100M	1.8306	3.2931	1.6422
	TYFR450100	450mm × 100M	2.664	4.3655	2.1795
	TYFR500100	500mm × 100M	3.559	6.2162	3.0885
	TYFR050200	50mm × 200M	0.0354	0.0327	0.0141
	TYFR075200	75mm × 200M	0.0811	0.0342	0.016
	TYFR100200	100mm × 200M	0.1326	0.0557	0.027
	TYFR150200	150mm × 200M	0.2326	0.0977	0.0474
	TYFR200200	200mm × 200M	0.7326	1.0977	0.5474
	TYFR250200	250mm × 200M	1.0576	1.7477	0.8724
	TYFR300200	300mm × 200M	1.4326	2.4977	1.2474
	TYFR350200	350mm × 200M	1.6326	2.7977	1.4474
	TYFR400200	400mm × 200M	1.8306	3.2931	1.6422
Sterilization Rolls, Gusseted	TYGR075100	75mm × 35mm × 100M	0.1966	0.0434	0.012
	TYGR100100	100mm × 40mm × 100M	0.2592	0.0488	0.0146
	TYGR150100	150mm × 50mm × 100M	0.5592	0.9488	0.2842
	TYGR200100	200mm × 50mm × 100M	0.7592	1.5488	0.4842
	TYGR250100	250mm × 60mm × 100M	1.1592	2.7488	0.8842
	TYGR300100	300mm × 70mm × 100M	1.4592	3.6488	1.1842
	TYGR350100	350mm × 80mm × 100M	1.7959	4.1601	1.8547
	TYGR400100	400mm × 80mm × 100M	2.0685	4.5816	2.5917

5.6 Comparison of Technological Characteristics

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 5-2**.

Table 5-2 Summary of the Proposed and Predicate Devices Technological Characteristics

Feature	Proposed device	Predicate device	Comparison																																																				
Device name	Sterilization Pouch/Roll Made with Tyvek® (K180672)	Sterilization Pouch/Roll Made with Tyvek® (K133838)																																																					
Material Composition	Tyvek®, PET, PE, Water, CH3COOH, Alcohol, n-Heptane adhesive, Hydrogen peroxide vapor Process Indicator Print Ink	Tyvek®, PET, PE, Water, CH3COOH, Alcohol, n-Heptane adhesive, Hydrogen peroxide vapor Process Indicator Print Ink	Same																																																				
Intended use	Sterilization Pouch/Roll Made with Tyvek® are intended to provide health care workers with an effective method to enclose devices intended for sterilization in the STERRAD® 100S Sterilizer. 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 sterilization. The pouches and rolls are printed with a chemical indicator bar which is a process indicator (ISO 11140-1:2005) that changes from red to blue (or lighter) when exposed to hydrogen peroxide vapor during processing in the STERRAD® 100S Sterilizer.	Sterilization Pouch/Roll Made with Tyvek® are intended to provide health care workers with an effective method to enclose devices intended for sterilization in the STERRAD® 100S Sterilizer. 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 sterilization. The pouches and rolls are printed with a chemical indicator bar which is a process indicator (ISO 11140-1:2005) that changes from red to blue (or lighter) when exposed to hydrogen peroxide vapor during processing in the STERRAD® Sterilization System.	Same																																																				
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>Dimensions (mm)</th></tr><tr><td>TYSE057133</td><td>57mm×133mm</td></tr><tr><td>TYSE090162</td><td>90mm×162mm</td></tr><tr><td>TYSE090256</td><td>90 mm×256 mm</td></tr><tr><td>TYSE070257</td><td>70mm×257mm</td></tr><tr><td>TYSE090257</td><td>90mm×257mm</td></tr><tr><td>TYSE133282</td><td>133 mm×282 mm</td></tr><tr><td>TYSE135283</td><td>135mm×283mm</td></tr><tr><td>TYSE135335</td><td>135mm×335mm</td></tr><tr><td>TYSE190358</td><td>190mm×358mm</td></tr><tr><td>TYSE254408</td><td>254 mm×408 mm</td></tr><tr><td>TYSE300380</td><td>300mm×380mm</td></tr><tr><td>TYSE300474</td><td>300mm×474mm</td></tr><tr><td>TYSE305485</td><td>305 mm × 485 mm</td></tr></table>	Self-sealing Sterilization Pouches		Model	Dimensions (mm)	TYSE057133	57mm×133mm	TYSE090162	90mm×162mm	TYSE090256	90 mm×256 mm	TYSE070257	70mm×257mm	TYSE090257	90mm×257mm	TYSE133282	133 mm×282 mm	TYSE135283	135mm×283mm	TYSE135335	135mm×335mm	TYSE190358	190mm×358mm	TYSE254408	254 mm×408 mm	TYSE300380	300mm×380mm	TYSE300474	300mm×474mm	TYSE305485	305 mm × 485 mm	<table><tr><th colspan="2">Self-sealing Sterilization Pouches</th></tr><tr><th>Model</th><th>Dimensions (mm)</th></tr><tr><td>TYSE057133</td><td>57mm×133mm</td></tr><tr><td>TYSE090162</td><td>90mm×162mm</td></tr><tr><td>TYSE070257</td><td>70mm×257mm</td></tr><tr><td>TYSE090257</td><td>90mm×257mm</td></tr><tr><td>TYSE135283</td><td>135mm×283mm</td></tr><tr><td>TYSE135335</td><td>135mm×335mm</td></tr><tr><td>TYSE190358</td><td>190mm×358mm</td></tr><tr><td>TYSE300380</td><td>300mm×380mm</td></tr><tr><td>TYSE300474</td><td>300mm×474mm</td></tr></table>	Self-sealing Sterilization Pouches		Model	Dimensions (mm)	TYSE057133	57mm×133mm	TYSE090162	90mm×162mm	TYSE070257	70mm×257mm	TYSE090257	90mm×257mm	TYSE135283	135mm×283mm	TYSE135335	135mm×335mm	TYSE190358	190mm×358mm	TYSE300380	300mm×380mm	TYSE300474	300mm×474mm	The models (dimensions) of type "Self-Sealing Sterilization Pouches" are different. There are 4 additional models in Proposed device. The additional models (Type, Model and Dimension) of Proposed device are shown in Table 5-3.
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Table 5-2. (Continued) Summary of the Proposed and Predicate Devices Technological Characteristics

Feature	Proposed device: Sterilization Pouch/Roll Made with Tyvek® (K180672)	Predicate devices: Sterilization Pouch/Roll Made with Tyvek® (K133838)	comparison																																																																																																																																														
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TYFP150255	150 mm × 255 mm																																																																																																																																																
TYFP150300	150mm×300mm																																																																																																																																																
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There are 5 additional models in Proposed device. The additional models (Type, Model and Dimension) of Proposed device are shown in Table 5-3.
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Table 5-2. (Continued) Summary of the Proposed and Predicate Devices Technological Characteristics

Feature	Proposed device: Sterilization Pouch/Roll Made with Tyvek® (K180672)	Predicate devices: Sterilization Pouch/Roll Made with Tyvek® (K133838)	com-parison																																								
Device models (Configurations/Dimensions)	<table><tr><th colspan="2">Sterilization Rolls, Gusseted</th></tr><tr><th>Model</th><th>Dimensions (mm)</th></tr><tr><td>TYGR075100</td><td>75mm × 35mm × 100M</td></tr><tr><td>TYGR100100</td><td>100mm × 40mm × 100M</td></tr><tr><td>TYGR150100</td><td>150mm × 50mm × 100M</td></tr><tr><td>TYGR200100</td><td>200mm × 50mm × 100M</td></tr><tr><td>TYGR250100</td><td>250mm × 60mm × 100M</td></tr><tr><td>TYGR300100</td><td>300mm × 70mm × 100M</td></tr><tr><td>TYGR350100</td><td>350mm × 80mm × 100M</td></tr><tr><td>TYGR400100</td><td>400mm × 80mm × 100M</td></tr></table>	Sterilization Rolls, Gusseted		Model	Dimensions (mm)	TYGR075100	75mm × 35mm × 100M	TYGR100100	100mm × 40mm × 100M	TYGR150100	150mm × 50mm × 100M	TYGR200100	200mm × 50mm × 100M	TYGR250100	250mm × 60mm × 100M	TYGR300100	300mm × 70mm × 100M	TYGR350100	350mm × 80mm × 100M	TYGR400100	400mm × 80mm × 100M	<table><tr><th colspan="2">Sterilization Rolls, Gusseted</th></tr><tr><th>Model</th><th>Dimensions (mm)</th></tr><tr><td>TYGR075100</td><td>75mm × 35mm × 100M</td></tr><tr><td>TYGR100100</td><td>100mm × 40mm × 100M</td></tr><tr><td>TYGR150100</td><td>150mm × 50mm × 100M</td></tr><tr><td>TYGR200100</td><td>200mm × 50mm × 100M</td></tr><tr><td>TYGR250100</td><td>250mm × 60mm × 100M</td></tr><tr><td>TYGR300100</td><td>300mm × 70mm × 100M</td></tr><tr><td>TYGR350100</td><td>350mm × 80mm × 100M</td></tr><tr><td>TYGR400100</td><td>400mm × 80mm × 100M</td></tr></table>	Sterilization Rolls, Gusseted		Model	Dimensions (mm)	TYGR075100	75mm × 35mm × 100M	TYGR100100	100mm × 40mm × 100M	TYGR150100	150mm × 50mm × 100M	TYGR200100	200mm × 50mm × 100M	TYGR250100	250mm × 60mm × 100M	TYGR300100	300mm × 70mm × 100M	TYGR350100	350mm × 80mm × 100M	TYGR400100	400mm × 80mm × 100M	Same
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Sterilization cycle	STERRAD® 100S Cycle The recommended Gas Plasma Sterilization Cycle parameters are exposure time: 6 minutes (Injection volume: 2880 μ L), exposure Temperature: 50℃, Plasma Stage – Delivered power: 400 Watt.	STERRAD® 100S Cycle The recommended Gas Plasma Sterilization Cycle parameters are exposure time: 6 minutes (Injection volume: 2880 μ L), exposure Temperature: 50℃, Plasma Stage – Delivered power: 400 Watt.	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 Tyvek® and used to seal the pouch. Release Tyvek® used in the pouch is a laminated sheet with composing structure of Tyvek®, PET, PE. It is a strip to cover the adhesive area and is released before seal the pouch. The Tyvek® conforms to recognized material standards and can be sterilized by Gas plasma. The Process Indicators Ink printed on the Tyvek® will exhibit a color change after the pouch is exposed to Gas plasma. 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 used. Sterilization rolls, Flat: These rolls are made from a Tyvek® 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 Tyvek® are the same with the self-sealing sterilization pouches. 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, 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 Tyvek® and used to seal the pouch. Release Tyvek® used in the pouch is a laminated sheet with composing structure of Tyvek®, PET, PE. It is a strip to cover the adhesive area and is released before seal the pouch. The Tyvek® conforms to recognized material standards and can be sterilized by Gas plasma. The Process Indicators Ink printed on the Tyvek® will exhibit a color change after the pouch is exposed to Gas plasma. 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 used. Sterilization rolls, Flat: These rolls are made from a Tyvek® 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 Tyvek® are the same with the self-sealing sterilization pouches. 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, 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																																								
Chemical Indicator Device De-	The color of the Chemical Indicator changes from red to blue (or lighter) when exposed to hydrogen peroxide.	The color of the Chemical Indicator changes from red to blue (or lighter) when exposed to hydrogen peroxide.	Same																																								

SECTION 5**K180672 510(K) SUMMARY**

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Note: Tyvek® is a registered trademark of Du Pont.

Table 5-2. (Continued) Summary of the Proposed and Predicate Devices Technological Characteristics

Feature		Proposed device: Sterilization Pouch/Roll Made with Tyvek® (K180672)	Predicate devices: Sterilization Pouch/Roll Made with Tyvek® (K133838)	comparison
Performance Testing				
Sterilant Penetration	Half-Cycle Efficacy	Showed a 6 log reduction of <i>Geobacillus stearothermophilus</i>	Showed a 6 log reduction of <i>Geobacillus stearothermophilus</i>	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
Package Integrity (Physical Properties) Tests conducted on unaged and aged (3 years accelerated aging) devices, before and after sterilization	Thickness Variations <i>ASTM F 2251</i>	Passed	Passed	Same
	Tensile strength of plastic film * <i>ASTM D882</i>	Passed	Passed	Same
	Tensile strength of Tyvek® * <i>ASTM D 5035</i>	Passed	Passed	Same
	Tear Resistance * <i>ASTM D1922</i>	Passed	Passed	Same
	Burst Strength <i>ASTM F1140</i>	Passed	Passed	Same
	Seal Peel Test <i>ASTM F88/F88M; ISO 11607-1</i>	Passed	Passed	Same
	Dye penetration Test (Seal Integrity Test) <i>ASTM F 1929; ISO 11607-1</i>	Passed	Passed	Same
	Microbial Barrier Test * <i>DIN 58953-6</i>	Passed	Passed	Same
Toxicological Properties (Biocompatibility Tests; skin irritation) <i>ANSI/AAMI/ISO 10993-10</i>		Test article with indicator dye was non-irritating	Test article with indicator dye was non-irritating	Same
Durability: Accelerated Aging Test <i>ASTM F 1980; ISO 11607-1</i>		Passed	Passed	Same
End Point / Post Processing Color Stability		Indicator dye remained stable following 3 years real-time aging	Indicator dye remained stable following 3 years real-time aging	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.

Table 5-3. Additional models of Sterilization Pouch/Roll Made with Tyvek®
(Type, Model and Dimension)

Type	Model	Dimensions (mm)
Self-Sealing Sterilization Pouches	TYSE090256	90 mm×256 mm
	TYSE133282	133 mm×282 mm
	TYSE254408	254 mm×408 mm
	TYSE305485	305 mm × 485 mm
Sterilization Pouches, Flat	TYFP150255	150 mm × 255 mm
	TYFP190330	190 mm × 330 mm
Sterilization Rolls, Flat	TYFR022f	50.8 mm × 61 M
	TYFR042f	101.6 mm × 61 M
	TYFR062f	152.4 mm×61 M
	TYFR082f	203.2 mm× 61 M
	TYFR102f	254 mm × 61 M

5.7 Summary of Non-Clinical Testing

The Sterilization Pouch/Roll Made with Tyvek® 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, Biocompatibility, Package Integrity, Material Compatibility, Sterility Maintenance, and Chemical Indicator Efficacy.

The results of the Sterilization Pouch/Roll Made with Tyvek® validation studies demonstrate that the sterilization pouches perform as intended. The results are summarized as follows:

- The Sterilant Penetration testing performed as described in AAMI / ANSI / ISO 14937:2009, “Sterilization of Health Care Products – General Requirements for Characterization of a Sterilizing Agent and the Development, Validation, and Routine Control of a Sterilization Process for Medical Devices”. The results confirm that the sterilant is able to penetrate the Sterilization Pouch/Roll Made with Tyvek® and sustain direct contact with the medical instrument inside the subject device.
- The Biocompatibility testing performed as described in ISO 10993-10 Third Edition 2010-08-01, “Biological Evaluation of Medical Devices – Part 10: Tests for irritation and skin sensitization”. The testing results demonstrate the Sigma Sterilization Pouch/Roll Made with Tyvek® showed “negative reaction”. And the Sterilization Pouch/Roll Made with Tyvek® meets the requirements ISO 10993-10:2010(E).
- 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 of the Sterilization Pouch/Roll Made with Tyvek® met the package integrity, material compatibility, and sterility maintenance testing acceptance criteria for each test mentioned above.
- 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”. The testing demonstrates the ability of the Sterilization Pouch/Roll Made with Tyvek® to effectively stability of the Process Indicators Ink before use, the lasting quality (color stability) of the color change, the completeness and uniformity of the color change and color change is all or none at the conditions measured, unless a color standard is provided on the indicator.

5.8 Conclusion:

The conclusions drawn from the non-clinical tests demonstrate that the proposed device is as safe, as effective, and performs as well as or better than the predicate device K133838.