DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

March 11, 2015

Sigma Medical Supplies Corp.
Mr. Uta Shih
Official Correspondent
C/O Sen Mu Technology Co., Ltd
15-2, Ln 26, Mineyuan 1st Rd, Lingya District
Kaohsiung, 802, Taiwan (R.O.C)

Re: K133838
Trade/Device Name: Sterilization Pouch/Roll Made with Tyvek® (Type: Self-sealing sterilization pouches; Sterilization Pouches, Flat; Sterilization Pouches, Gusseted; Sterilization Rolls, Flat; Sterilization Rolls, Gusseted)
Regulation Number: 21 CFR 880.6850
Regulation Name: Sterilization Wrap
Regulatory Class: II
Product Code: FRG
Dated: January 27, 2015
Received: February 9, 2015

Dear Mr. 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 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.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Tejashri Purohit-Sheth, M.D.

Tejashri Purohit-Sheth, M.D.
Clinical Deputy Director
DAGRID/ODE/CDRH FOR

Erin I. Keith, M.S.
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: K133838

Device Name: Sterilization Pouch/Roll Made with Tyvek®
(Type: Self-sealing sterilization pouches; Sterilization Pouches, Flat; Sterilization Pouches, Gusseted; Sterilization Rolls, Flat; Sterilization Rolls, Gusseted)

Indications for 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.

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

Prescription Use _____ (Per 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use__×__ (Per 21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

The following table (Table 4-1) lists the model numbers of the Sterilization Pouch/Roll Made with Tyvek® by type, model, dimensions and characteristics:

Table 4-1. The model numbers of Sterilization Pouch/Roll Made with Tyvek®
(Type, Model, Dimension and Characteristics)

Type	Model	Dimensions (mm)	Characteristics
Self-sealing Sterilization Pouches	TYSE057133	57mmx133mm	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.
	TYSE090162	90mmx162mm	
	TYSE070257	70mmx257mm	
	TYSE090257	90mmx257mm	
	TYSE135283	135mmx283mm	
	TYSE135335	135mmx335mm	
	TYSE190358	190mmx358mm	
	TYSE300380	300mmx380mm	
	TYSE300474	300mmx474mm	
Sterilization Pouches, Flat	TYFP075200	75mmx200mm	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.
	TYFP075300	75mmx300mm	
	TYFP100200	100mmx200mm	
	TYFP100300	100mmx300mm	
	TYFP150300	150mmx300mm	
	TYFP200400	200mmx400mm	
	TYFP250450	250mmx450mm	
	TYFP300500	300mmx500mm	
Sterilization Pouches, Gusseted	TYGP100300	100mmx40mm300mm	These rolls 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.
	TYGP150400	150mmx50mmx400mm	
	TYGP200400	200mmx50mmx400mm	
	TYGP250480	250mmx60mmx480mm	
	TYGP300500	300mmx70mmx500mm	

Type	Model	Dimensions (mm)	Characteristics
Sterilization Rolls, Flat	TYFR050070	50mmx70M	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.
	TYFR075070	75mmx70M	
	TYFR100070	100mmx70M	
	TYFR150070	150mmx70M	
	TYFR200070	200mmx70M	
	TYFR250070	250mmx70M	
	TYFR300070	300mmx70M	
	TYFR350070	350mmx70M	
	TYFR400070	400mmx70M	
	TYFR450070	450mmx70M	
	TYFR500070	500mmx70M	
	TYFR050100	50mmx100M	
	TYFR075100	75mmx100M	
	TYFR100100	100mmx100M	
	TYFR150100	150mmx100M	
	TYFR200100	200mmx100M	
	TYFR250100	250mmx100M	
	TYFR300100	300mmx100M	
	TYFR350100	350mmx100M	
	TYFR400100	400mmx100M	
	TYFR450100	450mmx100M	
	TYFR500100	500mmx100M	
	TYFR050200	50mmx200M	
	TYFR075200	75mmx200M	
	TYFR100200	100mmx200M	
	TYFR150200	150mmx200M	
	TYFR200200	200mmx200M	
	TYFR250200	250mmx200M	
	TYFR300200	300mmx200M	
	TYFR350200	350mmx200M	
	TYFR400200	400mmx200M	
Sterilization Rolls, Gusseted	TYGR075100	75mmx35mmx100M	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.
	TYGR100100	100mmx40mmx100M	
	TYGR150100	150mmx50mmx100M	
	TYGR200100	200mmx50mmx100M	
	TYGR250100	250mmx60mmx100M	
	TYGR300100	300mmx70mmx100M	
	TYGR350100	350mmx80mmx100M	
	TYGR400100	400mmx80mmx100M	

510(K) Summary

5.0 Prepared Date: March 11, 2015.

5.1 Device Trade Name: Sterilization Pouch/Roll Made with Tyvek®
(Type: Self-sealing sterilization pouches; Sterilization Pouches, Flat; Sterilization Pouches, Gusseted; Sterilization Rolls, Flat; Sterilization Rolls, Gusseted)

5.2 Named and Address of Manufacturer: Sigma Medical Supplies Corporation
NO.34, Ding-Ping Road, Ruei Fang Industrial Park
Ruei Fang Dist., New Taipei City 224,Taiwan, R.O.C.

Establishment Registration Number: 3004970050

Contact Person: Rose Chien
Quality Assurance / Regulatory Affairs Manager

Tel: 886-2-24974121 ext. 283
Fax: 886-2-24974122
E-mail: qa_manager@sigma-medical.com.tw

5.3 Device Classification Names: 1) Sterilization wrap containers, trays, cassettes & accessories.
2) Indicator, Physical/Chemical Sterilization Process

Classification/Panel: Class II, 21CFR 880.6850

Classification Advisory Committee: General Hospital

Product Code: FRG

Recognized Performance Standard: ANSI/AAMI/ISO 11607-1:2006 (FRG)

5.4 Predicate Devices:
K103210, Tyvek® Pouch/Roll with STERRAD® Chemical Indicator (FRG)

5.5 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.

5.6 Device Description

Sterilization Pouch/Roll Made with Tyvek® is intended to be used to contain medical devices to be terminally sterilized in the STERRAD® Sterilization Systems. The recommended Gas Plasma sterilization cycle parameter is 6 minutes (Injection volume: 2880μ L) at 50℃. The medical devices are inserted into the Pouch/Roll, sealed, and then sterilized in the STERRAD® 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 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® Sterilization System.

The proposed pouches are constructed from Tyvek®/plastic films, with H_2O_2 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 H_2O_2 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. H_2O_2 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. 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 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 rolls 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 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 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 5-1) lists the model numbers of the Sterilization Pouch/Roll Made with Tyvek® by type, model, dimensions:

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

Type	Model	Dimensions (mm)
Self-sealing Sterilization Pouches	TYSE057133	57mmx133mm
	TYSE090162	90mmx162mm
	TYSE070257	70mmx257mm
	TYSE090257	90mmx257mm
	TYSE135283	135mmx283mm
	TYSE135335	135mmx335mm
	TYSE190358	190mmx358mm
	TYSE300380	300mmx380mm
	TYSE300474	300mmx474mm
Sterilization Pouches, Flat	Model	Dimensions (mm)
	TYFP075200	75mmx200mm
	TYFP075300	75mmx300mm
	TYFP100200	100mmx200mm
	TYFP100300	100mmx300mm
	TYFP150300	150mmx300mm
	TYFP200400	200mmx400mm
	TYFP250450	250mmx450mm
	TYFP300500	300mmx500mm
Sterilization Pouches, Gusseted	TYGP100300	100mmx40mm300mm
	TYGP150400	150mmx50mmx400mm
	TYGP200400	200mmx50mmx400mm
	TYGP250480	250mmx60mmx480mm
	TYGP300500	300mmx70mmx500mm

Type	Model	Dimensions (mm)
Sterilization Rolls, Flat	TYFR050070	50mmx70M
	TYFR075070	75mmx70M
	TYFR100070	100mmx70M
	TYFR150070	150mmx70M
	TYFR200070	200mmx70M
	TYFR250070	250mmx70M
	TYFR300070	300mmx70M
	TYFR350070	350mmx70M
	TYFR400070	400mmx70M
	TYFR450070	450mmx70M
	TYFR500070	500mmx70M
	TYFR050100	50mmx100M
	TYFR075100	75mmx100M
	TYFR100100	100mmx100M
	TYFR150100	150mmx100M
	TYFR200100	200mmx100M
	TYFR250100	250mmx100M
	TYFR300100	300mmx100M
	TYFR350100	350mmx100M
	TYFR400100	400mmx100M
	TYFR450100	450mmx100M
	TYFR500100	500mmx100M
	TYFR050200	50mmx200M
	TYFR075200	75mmx200M
	TYFR100200	100mmx200M
	TYFR150200	150mmx200M
	TYFR200200	200mmx200M
	TYFR250200	250mmx200M
	TYFR300200	300mmx200M
	TYFR350200	350mmx200M
	TYFR400200	400mmx200M

Type	Model	Dimensions (mm)
Sterilization Rolls, Gusseted	TYGR075100	75mmx35mmx100M
	TYGR100100	100mmx40mmx100M
	TYGR150100	150mmx50mmx100M
	TYGR200100	200mmx50mmx100M
	TYGR250100	250mmx60mmx100M
	TYGR300100	300mmx70mmx100M
	TYGR350100	350mmx80mmx100M
	TYGR400100	400mmx80mmx100M

5.7 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 5-2.**

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

<table>
<tr><th>Device</th><th>New Device</th><th>Predicate Devices</th></tr>
<tr><td>Device name</td><td>Sterilization Pouch/Roll Made with Tyvek®</td><td>Tyvek® Pouch/Roll with STERRAD® Chemical Indicator</td></tr>
<tr><td>510(k) number</td><td>K133838</td><td>K103210</td></tr>
<tr><td>Material Composition</td><td>Tyvek®, PET, PE, Water, CH3COOH, Alcohol, n-Heptane adhesive, Hydrogen peroxide vapor Process Indicator Print Ink</td><td>Tyvek®, PET, PE, Water, CH3COOH, Alcohol, n-Heptane adhesive, Hydrogen peroxide vapor Process Indicator Print Ink</td></tr>
<tr><td>Intended use</td><td>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.</td><td>Tyvek® Pouch/Roll with STERRAD® Chemical Indicator are intended to be used to enclose medical devices that are be terminally sterilized in the STERRAD® 100NX™ Sterilizer and to indicate, by color change, that the pouch has exposed to sterilant. After completion of sterilization process, the Pouch/Roll maintain sterility until the seal of the Pouch/Roll is opened.
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 yellow (or lighter) when exposed to hydrogen peroxide vapor processing in the STERRAD® Sterilization Systems.</td></tr>
<tr><td>Device models (Configurations/Dimensions)</td><td>
<table>
<tr><th colspan="2">Self-sealing Sterilization Pouches</th></tr>
<tr><td>Model</td><td>Dimensions (mm)</td></tr>
<tr><td>TYSE057133</td><td>57mmx133mm</td></tr>
<tr><td>TYSE090162</td><td>90mmx162mm</td></tr>
<tr><td>TYSE070257</td><td>70mmx257mm</td></tr>
<tr><td>TYSE090257</td><td>90mmx257mm</td></tr>
<tr><td>TYSE135283</td><td>135mmx283mm</td></tr>
<tr><td>TYSE135335</td><td>135mmx335mm</td></tr>
<tr><td>TYSE190358</td><td>190mmx358mm</td></tr>
<tr><td>TYSE300380</td><td>300mmx380mm</td></tr>
<tr><td>TYSE300474</td><td>300mmx474mm</td></tr>
</table>
<table>
<tr><th colspan="2">Sterilization Pouches, Flat</th></tr>
<tr><td>Model</td><td>Dimensions (mm)</td></tr>
<tr><td>TYFP075200</td><td>75mmx200mm</td></tr>
<tr><td>TYFP075300</td><td>75mmx300mm</td></tr>
<tr><td>TYFP100200</td><td>100mmx200mm</td></tr>
<tr><td>TYFP100300</td><td>100mmx300mm</td></tr>
<tr><td>TYFP150300</td><td>150mmx300mm</td></tr>
<tr><td>TYFP200400</td><td>200mmx400mm</td></tr>
<tr><td>TYFP250450</td><td>250mmx450mm</td></tr>
<tr><td>TYFP300500</td><td>300mmx500mm</td></tr>
</table>
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<table>
<tr><th colspan="2">Tyvek® Pouch with STERRAD® Chemical Indicator, Self Seal,</th></tr>
<tr><td>Model (Code)</td><td>Dimensions (mm)</td></tr>
<tr><td>12320</td><td>76mm x 203 mm</td></tr>
<tr><td>12326</td><td>102mm x 260 mm</td></tr>
<tr><td>12332</td><td>152mm x 318 mm</td></tr>
<tr><td>12335</td><td>102mm x 356 mm</td></tr>
<tr><td>12340</td><td>203mm x 406 mm</td></tr>
<tr><td>12342</td><td>152mm x 419 mm</td></tr>
<tr><td>12348</td><td>254mm x 483 mm</td></tr>
<tr><td>12356</td><td>318mm x 559 mm</td></tr>
</table>
<table>
<tr><th colspan="2">Tyvek® Pouch with STERRAD® Chemical Indicator, Heat Seal,</th></tr>
<tr><td>Model (Code)</td><td>Dimensions (mm)</td></tr>
<tr><td>12521</td><td>76mm x 203 mm</td></tr>
<tr><td>12526</td><td>102mm x 260 mm</td></tr>
<tr><td>12532</td><td>152mm x 318 mm</td></tr>
<tr><td>12541</td><td>203mm x 406 mm</td></tr>
<tr><td>12548</td><td>254mm x 483 mm</td></tr>
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<table>
<tr><th>Device</th><th>New Device</th><th>Predicate Devices</th></tr>
<tr>
<td>Device models (Configurations/Dimensions)</td>
<td>
<table>
<tr><th colspan="2">Sterilization Rolls, Flat</th></tr>
<tr><th>Model</th><th>Dimensions (mm)</th></tr>
<tr><td>TYFR050070</td><td>50mmx70M</td></tr>
<tr><td>TYFR075070</td><td>75mmx70M</td></tr>
<tr><td>TYFR100070</td><td>100mmx70M</td></tr>
<tr><td>TYFR150070</td><td>150mmx70M</td></tr>
<tr><td>TYFR200070</td><td>200mmx70M</td></tr>
<tr><td>TYFR250070</td><td>250mmx70M</td></tr>
<tr><td>TYFR300070</td><td>300mmx70M</td></tr>
<tr><td>TYFR350070</td><td>350mmx70M</td></tr>
<tr><td>TYFR400070</td><td>400mmx70M</td></tr>
<tr><td>TYFR450070</td><td>450mmx70M</td></tr>
<tr><td>TYFR500070</td><td>500mmx70M</td></tr>
<tr><td>TYFR050100</td><td>50mmx100M</td></tr>
<tr><td>TYFR075100</td><td>75mmx100M</td></tr>
<tr><td>TYFR100100</td><td>100mmx100M</td></tr>
<tr><td>TYFR150100</td><td>150mmx100M</td></tr>
<tr><td>TYFR200100</td><td>200mmx100M</td></tr>
<tr><td>TYFR250100</td><td>250mmx100M</td></tr>
<tr><td>TYFR300100</td><td>300mmx100M</td></tr>
<tr><td>TYFR350100</td><td>350mmx100M</td></tr>
<tr><td>TYFR400100</td><td>400mmx100M</td></tr>
<tr><td>TYFR450100</td><td>450mmx100M</td></tr>
<tr><td>TYFR500100</td><td>500mmx100M</td></tr>
<tr><td>TYFR050200</td><td>50mmx200M</td></tr>
<tr><td>TYFR075200</td><td>75mmx200M</td></tr>
<tr><td>TYFR100200</td><td>100mmx200M</td></tr>
<tr><td>TYFR150200</td><td>150mmx200M</td></tr>
<tr><td>TYFR200200</td><td>200mmx200M</td></tr>
<tr><td>TYFR250200</td><td>250mmx200M</td></tr>
<tr><td>TYFR300200</td><td>300mmx200M</td></tr>
<tr><td>TYFR350200</td><td>350mmx200M</td></tr>
<tr><td>TYFR400200</td><td>400mmx200M</td></tr>
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<table>
<tr><th colspan="2">Tyvek® Roll with STERRAD® Chemical Indicator</th></tr>
<tr><th>Model (Code)</th><th>Dimensions (mm)</th></tr>
<tr><td>12407</td><td>76mm x 70 M</td></tr>
<tr><td>12410</td><td>102mm x 70 M</td></tr>
<tr><td>12415</td><td>152mm x 70 M</td></tr>
<tr><td>12420</td><td>203mm x 70 M</td></tr>
<tr><td>12425</td><td>254mm x 70 M</td></tr>
<tr><td>12435</td><td>357mm x 70 M</td></tr>
<tr><td>12442</td><td>419mm x 70 M</td></tr>
<tr><td>12450</td><td>508mm x 70 M</td></tr>
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<table>
<tr><th>Device</th><th>New Device</th><th>Predicate Devices</th></tr>
<tr><td>Device models (Configurations/Dimensions)</td><td>
<table>
<tr><th colspan="2">Sterilization Rolls, Gusseted</th></tr>
<tr><td>Model</td><td>Dimensions (mm)</td></tr>
<tr><td>TYGR075100</td><td>75mmx35mmx100M</td></tr>
<tr><td>TYGR100100</td><td>100mmx40mmx100M</td></tr>
<tr><td>TYGR150100</td><td>150mmx50mmx100M</td></tr>
<tr><td>TYGR200100</td><td>200mmx50mmx100M</td></tr>
<tr><td>TYGR250100</td><td>250mmx60mmx100M</td></tr>
<tr><td>TYGR300100</td><td>300mmx70mmx100M</td></tr>
<tr><td>TYGR350100</td><td>350mmx80mmx100M</td></tr>
<tr><td>TYGR400100</td><td>400mmx80mmx100M</td></tr>
</table>
<table>
<tr><th colspan="2">Sterilization Pouches, Gusseted</th></tr>
<tr><td>Model</td><td>Dimensions (mm)</td></tr>
<tr><td>TYGP100300</td><td>100mmx40mm300mm</td></tr>
<tr><td>TYGP150400</td><td>150mmx50mmx400mm</td></tr>
<tr><td>TYGP200400</td><td>200mmx50mmx400mm</td></tr>
<tr><td>TYGP250480</td><td>250mmx60mmx480mm</td></tr>
<tr><td>TYGP300500</td><td>300mmx70mmx500mm</td></tr>
</table>
</td><td>N/A

N/A</td></tr>
<tr><td>Sterilization cycles</td><td>The recommended Gas Plasma Sterilization Cycle parameters are exposure time: 6 minutes (Injection volume: 2880μ L), exposure Temperature: 50℃, Plasma Stage – Delivered power: 450 Watt.</td><td>The recommended Gas Plasma Sterilization Cycle parameters are exposure time: 6 minutes (Injection volume: 2880μ L), exposure Temperature: 50℃, Plasma Stage – Delivered power: 450 Watt.</td></tr>
<tr><td>Design features</td><td>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 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 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 rolls 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.</td><td>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 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 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.
N/A

N/A</td></tr>
</table>

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

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 Sterilization Pouch/Roll Made with Tyvek® has many similar technological characteristics when compared to the predicate devices. The material composition of Sterilization Pouch/Roll Made with Tyvek® is similar to the predicate devices. Besides parameters of sterilization, the intended use of Sterilization Pouch/Roll Made with Tyvek® is similar to the predicate devices. The device models and design features of Self-sealing sterilization pouches, Sterilization pouches, Flat, and Sterilization rolls, Flat of The Sterilization Pouch/Roll Made with Tyvek® are similar to the predicate devices. The design features that Sterilization Pouch/Roll Made with Tyvek®'s external chemical ink indicators are designed to indicate to the user that the pouch has undergone the Gas Plasma sterilization process (hydrogen peroxide vapor) is also similar to the predicate devices.

The Sterilization Pouch/Roll Made with Tyvek® has some different design features from the predicate device. The Sterilization Pouch/Roll Made with Tyvek® is offered 5 types pouches, however, the predicate device is offered 3 types pouches. The Sterilization Pouch/Roll Made with Tyvek® is offered more two types which are Sterilization pouches, Gusseted and Sterilization rolls, Gusseted. The type of Sterilization pouches, Gusseted of Sterilization Pouch/Roll Made with Tyvek® is 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. The type of Sterilization rolls, Gusseted of Sterilization Pouch/Roll Made with Tyvek® is 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 complete substantial equivalence comparison table as follows:

PERFORMANCE		**NEW DEVICE**		**PREDICATE**	
Device		Sterilization Pouch/Roll Made with Tyvek® (Type: Self-sealing sterilization pouches; Sterilization Pouches, Flat; Sterilization Pouches, Gusseted; Sterilization Rolls, Flat; Sterilization Rolls, Gusseted)		Tyvek® Pouch/Roll with STERRAD® Chemical Indicator (Type: Self-sealing sterilization pouches; Sterilization Pouches, Flat; Sterilization Rolls, Flat)	
Sterilant Penetration	Gas plasma Sterilization Validation ANSI/AAMI/ISO 14937:2009	The test meet the requirement of SAL 10^{-6}		The test meet the requirement of SAL 10^{-6}	
Package Integrity (Physical Properties)		**Before Sterilization**	**After Gas plasma Sterilization**	**Before Sterilization**	**After Gas plasma Sterilization**
Thickness Variations (mm) *ASTM F 2251-03*	Small	0.145	0.145	0.143	0.143
	Large	0.146	0.146	0.147	0.145
Tear Resistance (g) * *ASTM D1922*		CD 259	CD 258	CD 262	CD 260
		MD 282	MD 280	MD 283	MD 281
Tensile strength of plastic film (kgf/mm2) * *ASTM D882*		CD 575	CD 531	CD 563	CD 527
		MD 577	MD 531	MD 556	MD 513

PERFORMANCE		NEW DEVICE		PREDICATE	
Tensile strength of Tyvek®		CD 174	CD 170	CD 175	CD 173
(N/2.54cm) * *ASTM D 5035*		MD 163	MD 162	MD 166	MD 164
Burst Strength (kPa)	Small	21.4	17.95	20.8	17.0
ASTM F1140-0 7	Large	4.49	2.03	4.1	2.0
Seal Peel Test (g/15mm) ASTM F88/F88M-09;*ISO 11607-1*	Small	Upper: 340.3 Down: 506.7 Left: 345.7 Right: 316.5 Result: Pass	Upper: 493.6 Down: 709.9 Left: 436.0 Right: 518.5 Result: Pass	Pass	Pass
	Large	Upper: 434.7 Down: 420.4 Left: 424.4 Right: 431.7 Result: Pass	Upper: 577.2 Down: 489.3 Left: 600.8 Right: 612.9 Result: Pass	Pass	Pass
Dye penetration Test *ASTM F 1929-12;ISO 11607-1* (Seal Integrity Test)		No Channels identified on package	No Channels identified on package	No Channels identified on package	No Channels identified on package
Microbial Barrier Test **DIN 58953-6:2010-05*	Small	N/A	< 1 Result: Pass	N/A	Pass
	Large	N/A	< 1 Result: Pass	N/A	Pass
Toxicological Properties (Biocompatibility, Tests for Tests for irritation and skin sensitization) *ANSI/AAMI/ISO 10993-10*		Negative reaction	Negative reaction	**Toxicological Properties** (Biocompatibility, Tests for Tests for irritation and skin sensitization) *ANSI/AAMI/ISO 10**993-10***	Negative reaction
Durability: Accelerated Aging Test *ASTM F 1980-2007; ISO 11607-1 2006*		3 Years	1Years	**Durability: Accelerated Aging Test** *ASTM F 1980-2007; ISO 11607-1 2006*	3 Years
Shelf Life		3 Years	1Years	**Shelf Life**	3 Years

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

The applicant device is **Substantially Equivalent (SE)** to the predicate device in terms of Effectiveness and Safety.

Effectiveness and Safety

The Sterilization Pouch/Roll Made with Tyvek® has the identical intended use and indication for use as the predicate devices. Substantial equivalence to predicate devices was established by testing the Sterilant Penetration, Biocompatibility, Package Integrity, Material Compatibility, Sterility Maintenance, and Chemical Indicator Efficacy.

The Sterilization Pouch/Roll Made with Tyvek® validates its effectiveness and safety using recommended practice, standards and guidelines developed by independent organizations such as the Association for the advancement of Medical Instrumentation (AAMI), International Organization for Standardization (ISO), and American Society for Testing and Materials (ASTM). The Sterilization Pouch/Roll Made with Tyvek® was validated to meet the requirements of AAMI / ANSI / ISO 11607-1:2006/(R) 2010, March 2012.

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. The testing results demonstrate the ability of the Sterilization Pouch/Roll Made with Tyvek® to effectively adequate sterilant penetration to the most difficult areas to reach inside the packaging. 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 package.
- The Biocompatibility testing performed as described in ISO 10993-10 Third Edition 2010-08-01**.** The testing results demonstrate the Sigma Sterilization Pouch and Roll 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/(R) 2010**,** ASTM D882, ISO 1924-2, ASTM D 5035, ASTM F 2251-03, ASTM D 1922, ASTM D 1004, ASTM F 1140-07, ASTM F 1929-98 (04), ASTM F88/F88M-09, ASTM F 1980-2007, ASTM F 1608-00, DIN 58953-6:2010-05.The testing results demonstrate the ability of the Sterilization Pouch/Roll Made with Tyvek® to effectively adequate Package Integrity.
- The Chemical Indicator Efficacy testing performed as described in AAMI / ANSI / ISO 11140-1:2005. 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. And the Sterilization Pouch/Roll Made with Tyvek® meets the requirements ISO 11140-1:2005.

Conclusion:

Basis for Determination of Substantial Equivalence: Based on the intended use, indications for use, technological characteristics, performance data and nonclinical tests performed, the subject Sterilization Pouch/Roll Made with Tyvek® is substantially equivalent and is as safe and as effective as the legally marketed predicate devices, K103210, Tyvek® Pouch/Roll with STERRAD® Chemical Indicator (FRG).