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

June 23, 2017

Medline Industries, Inc.
Jennifer Mason
Senior Regulatory Affairs Specialist
One Medline Place
Mundelein, Illinois 60060

Re: K162993
Trade/Device Name: Gemini Sterilization Wrap
Regulation Number: 21 CFR 880.6850
Regulation Name: Sterilization Wrap
Regulatory Class: Class II
Product Code: FRG
Dated: May 16, 2017
Received: June 25, 2017

Dear Jennifer Mason:

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 Industry and Consumer Education 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" (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.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education 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,

Lori A. Wiggins -S6

Lori A. Wiggins, MPT, CLT
Acting Director
Division of Anesthesiology,
General Hospital, Respiratory,
Infection Control, and Dental Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K162993

Device Name
Gemini Sterilization Wrap

Indications for Use *(Describe)*
Gemini Sterilization Wraps are intended to be used to enclose another medical device that is to be sterilized by a health care provider. It is intended to allow sterilization of the enclosed medical device and also to maintain sterility of such content until used. Gemini Sterilization Wrap is validated for use in the following sterilization processes modes and cycles:

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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TABLE 1: STERIS V-PRO® Low Temperature Sterilization Systems. The wrap was validated to be effectively aerated during the pre-programmed cycles

Gemini Wrap Model	Gemini Wrap Weight	STERIS V-PRO® Low Temperature Sterilization Cycles
GEM11XX/GEM11XXS/GEM11XXT	Lightweight	▪ STERIS V-PRO® 60 (Lumen, Non-Lumen and Flexible Cycles) ▪ STERIS V-PRO® 1 (Lumen Cycle) (per K150698) ▪ STERIS V-PRO® 1 Plus (Lumen and Non-Lumen Cycle) (per K150698) ▪ STERIS V-PRO® maX (Lumen, Non-Lumen, and Flexible Cycle)(per K150698)
GEM21XX/GEM11XXS/GEM11XXT	Regular Weight	
GEM31XX/GEM31XXS/GEM31XXT	Medium Weight	
GEM41XX/GEM41XXS/GEM41XXT	Heavyweight	
GEM51XX/GEM51XXS/GEM51XXT	Super Heavyweight	

TABLE 2: STERIZONE® VP4 Sterilization System

Gemini Wrap Model	Gemini Wrap Weight	STERIZONE® VP4 Sterilization System
GEM11XX/GEM11XXS/GEM11XXT	Lightweight	▪ STERIZONE® VP4 Sterilizer single preset sterilization cycle
GEM21XX/GEM11XXS/GEM11XXT	Regular Weight	
GEM31XX/GEM31XXS/GEM31XXT	Medium Weight	
GEM41XX/GEM41XXS/GEM41XXT	Heavyweight	
GEM51XX/GEM51XXS/GEM51XXT	Super Heavyweight	

TABLE 3: Wrap Model Recommendations[1]

Gemini Wrap Weight	Gemini Wrap Model	Intended Load	Maximum Recommended Wrapped Package Content[2]		
			STERIS V-PRO® 1, 1Plus, maX	STERIS V-PRO 60®	STERIZONE® VP4 Sterilizer
Light Weight	GEM1	Light weight package (for example: standard linen packs)	6.5 lbs.	6 lbs.	6 lbs.
Regular Weight	GEM2	Light to moderate weight package (for example: general use medical instruments)	9 lbs.	9 lbs.	9 lbs.
Medium Weight	GEM3	Moderate to heavy weight package (for example: general use medical instruments)	10 lbs.	13 lbs.	13 lbs.
Heavy Weight	GEM4	Heavy weight package (for	10 lbs.	17 lbs.	17 lbs.

		example: general use medical instruments)			
Super Heavy Weight	GEM5	Very heavy weight package (for example: general use medical instruments)	10 lbs.	25 lbs.	25 lbs.

The following loads were used in STERIS V-PRO® 1, 1Plus, maX Sterility Maintenance Validation Studies:

- GEM1: 2.5 lbs. metal mass, 6 forceps, STERIS V-PRO® Tray (17 in. x 10 in. x 3.5 in.) at 4 lbs.
- GEM2: 5 lbs. metal mass, 6 forceps, STERIS V-PRO® Tray (17 in. x 10 in. x 3.5 in.) at 4 lbs.
- GEM3: 6 lbs. metal mass, 6 forceps, STERIS V-PRO® Tray (17 in. x 10 in. x 3.5 in.) at 4 lbs.
- GEM4: 5 lbs. metal mass, 6 forceps, STERIS V-PRO® Tray (21 in. x 10 in. x 3.5 in.) at 5 lbs.
- GEM5: 5 lbs. metal mass, 6 forceps, STERIS V-PRO® Tray (21 in. x 10 in. x 3.5 in.) at 5 lbs.

The following loads were used in STERIS V-PRO® 60 Sterility Maintenance Validation Studies:

- GEM1 – GEM5: V-PRO® Tray (10 in. x 21 in. x 3.5 in.), metal mass to make final total weight tested above, and 6 forceps.

The follow loads were used in STERIZONE® VP4 Sterility Maintenance Validation Studies:

- GEM1-GEM2: Symmetry Medical – MicroPack® Plastic Tray (15 in. x 10 in. x 1.5 in.), metal and non-metal instruments to make final total weight recommended above.
- GEM3-GEM5: SteriPack Metal Tray (23 in. x 11 in. x 5 in.), metal and non-metal instruments to make final total weight tested recommended above.

[1] Individual results may differ due to factors such as variations in handling practices, wrapping techniques and folding methods. Results may also differ due to the use of irregularly shaped contents, which may put added stress on the wrap. Each healthcare facility should determine for itself which wrap model is most appropriate for each intended use.

[2] It is recommended to not exceed the maximum wrapped package content weights indicated for each wrap model. Furthermore it is recommended to not exceed the number, weight and sizes of individual content types that were validated for the Gemini Sterilization Wrap (i.e.: the weight of the metal mass)

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SECTION 5

510(k) SUMMARY (K162993)

[AS REQUIRED BY 21CFR807.92(c)]

Submitter / 510(k) Sponsor

Medline Industries, Inc.
1 Medline Place
Mundelein, IL 60060

Registration Number: 1417592

Contact Person

Jennifer Mason
Senior Regulatory Affairs Specialist
Phone: 847-643-3652
Email: jamason@medline.com

Summary Preparation Date

June 21, 2017

Type of 510(k) Submission

Traditional

Device Name / Classification

Name of Device: Gemini Sterilization Wrap
Proprietary Name: Sterilization Wrap
Common Name: Sterilization Wrap
Classification Name: Wrap, Sterilization
Product Code: FRG
Classification Panel:
Regulatory Class: II
Regulation #: 21 CFR 880.6850

Predicate Device

Gemini Sterilization Wrap
K150698

Reference Devices

Gemini Sterilization Wrap
K152564

Medline Industries, Inc.
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Gemini Bonded Sterilization Wrap
K152458

Device Description

Gemini Sterilization Wraps are offered to the market place as bulk packages of single and two ply bonded sheets of wrap for use by customers in accordance with standard hospital practices which require that two sheets are used each time a medical device or collections of medical devices are wrapped. The bonded wrap is comprised of two sheets of Gemini Sterilization Wrap ultrasonically seamed on two parallel sides. This allows for convenient wrapping with two sheets simultaneously.

Gemini Sterilization Wrap items are square or rectangular sheets of non-woven fabric produced using a five-layer SSMMS (spunbond-spunbond-meltblown-meltblown-spunbond) process.

The standard blue wrap fabric is made of polypropylene with the addition of less than 2% of phthalocyanine blue pigmentation and less than 0.35% titanium dioxide white pigmentation. The wraps are offered in 3 different shades of blue that vary in the amount of phthalocyanine blue pigmentation depending on the weight of the wrap. Also, some wraps contain titanium dioxide and others do not. A detailed description of material composition can be found in the Device Description section.

The two-tone blue/pink wrap fabric is made of polypropylene with the addition of less than 2% phthalocyanine blue pigmentation, less than 0.5% of titanium dioxide white pigmentation and less than 2% of disazocondensation red pigmentation. The two-tone blue/pink wraps are offered in 3 different shades of blue and pink that vary in the amount of phthalocyanine, disazocondensation red and titanium dioxide depending on the weight of the wrap. A detailed description of material composition can be found in the Device Description section.

Gemini Sterilization Wrap is available in sizes ranging from 12” x 12” to 54” x 72” across five different material weights/models listed below. Photos showing the different material weights are listed in Figure 1 and Figure 2 below. Additional product and size information is provided in Table 1 below. The material composition of the Gemini Sterilization Wrap is listed in Table 2. Details on the product variations and composition are also provided with Appendix B.

Indications for Use

Gemini Sterilization Wraps are intended to be used to enclose another medical device that is to be sterilized by a health care provider. It is intended to allow sterilization of the enclosed medical device and also to maintain sterility of such content until used. Gemini Sterilization Wrap is validated for use in the following sterilization processes modes and cycles:

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TABLE 1: STERIS V-PRO® Low Temperature Sterilization Systems. The wrap was validated to be effectively aerated during the pre-programmed cycles

Gemini Wrap Model	Gemini Wrap Weight	STERIS V-PRO® Low Temperature Sterilization Cycles
GEM11XX/GEM11XXS/GEM11XXT	Lightweight	▪ STERIS V-PRO® 60 (Lumen, Non-Lumen and Flexible Cycles) ▪ STERIS V-PRO® 1 (Lumen Cycle) (per K150698) ▪ STERIS V-PRO® 1 Plus (Lumen and Non-Lumen Cycle) (per K150698) ▪ STERIS V-PRO® maX (Lumen, Non-Lumen, and Flexible Cycle)(per K150698)
GEM21XX/GEM11XXS/GEM11XXT	Regular Weight	
GEM31XX/GEM31XXS/GEM31XXT	Medium Weight	
GEM41XX/GEM41XXS/GEM41XXT	Heavyweight	
GEM51XX/GEM51XXS/GEM51XXT	Super Heavyweight	

TABLE 2: STERIZONE® VP4 Sterilization System

Gemini Wrap Model	Gemini Wrap Weight	STERIZONE® VP4 Sterilization System
GEM11XX/GEM11XXS/GEM11XXT	Lightweight	▪ STERIZONE® VP4 Sterilizer single preset sterilization cycle
GEM21XX/GEM11XXS/GEM11XXT	Regular Weight	
GEM31XX/GEM31XXS/GEM31XXT	Medium Weight	
GEM41XX/GEM41XXS/GEM41XXT	Heavyweight	
GEM51XX/GEM51XXS/GEM51XXT	Super Heavyweight	

TABLE 3: Wrap Model Recommendations[1]

Gemini Wrap Weight	Gemini Wrap Model	Intended Load	Maximum Recommended Wrapped Package Content[2]		
			STERIS V-PRO® 1, 1Plus, maX	STERIS V-PRO 60®	STERIZONE® VP4 Sterilizer
Light Weight	GEM1	Light weight package (for example: standard linen packs)	6.5 lbs.	6 lbs.	6 lbs.
Regular Weight	GEM2	Light to moderate weight package (for example: general use medical instruments)	9 lbs.	9 lbs.	9 lbs.
Medium Weight	GEM3	Moderate to heavy weight package (for	10 lbs.	13 lbs.	13 lbs.

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		example: general use medical instruments)			
Heavy Weight	GEM4	Heavy weight package (for example: general use medical instruments)	10 lbs.	17 lbs.	17 lbs.
Super Heavy Weight	GEM5	Very heavy weight package (for example: general use medical instruments)	10 lbs.	25 lbs.	25 lbs.

The following loads were used in STERIS V-PRO® 1, 1Plus, maX Sterility Maintenance Validation Studies:

- GEM1: 2.5 lbs. metal mass, 6 forceps, STERIS V-PRO® Tray (17 in. x 10 in. x 3.5 in.) at 4 lbs.
- GEM2: 5 lbs. metal mass, 6 forceps, STERIS V-PRO® Tray (17 in. x 10 in. x 3.5 in.) at 4 lbs.
- GEM3: 6 lbs. metal mass, 6 forceps, STERIS V-PRO® Tray (17 in. x 10 in. x 3.5 in.) at 4 lbs.
- GEM4: 5 lbs. metal mass, 6 forceps, STERIS V-PRO® Tray (21 in. x 10 in. x 3.5 in.) at 5 lbs.
- GEM5: 5 lbs. metal mass, 6 forceps, STERIS V-PRO® Tray (21 in. x 10 in. x 3.5 in.) at 5 lbs.

The following loads were used in STERIS V-PRO® 60 Sterility Maintenance Validation Studies:

- GEM1 – GEM5: V-PRO® Tray (10 in. x 21 in. x 3.5 in.), metal mass to make final total weight tested above, and 6 forceps.

The follow loads were used in STERIZONE® VP4 Sterility Maintenance Validation Studies:

- GEM1-GEM2: Symmetry Medical – MicroPack® Plastic Tray (15 in. x 10 in. x 1.5 in.), metal and non-metal instruments to make final total weight recommended above.
- GEM3-GEM5: SteriPack Metal Tray (23 in. x 11 in. x 5 in.), metal and non-metal instruments to make final total weight tested recommended above.

[1] Individual results may differ due to factors such as variations in handling practices, wrapping techniques and folding methods. Results may also differ due to the use of irregularly shaped contents, which may put added stress on the wrap. Each healthcare facility should determine for itself which wrap model is most appropriate for each intended use.

[2] It is recommended to not exceed the maximum wrapped package content weights indicated for each wrap model. Furthermore it is recommended to not exceed the number, weight and sizes of individual content types that were validated for the Gemini Sterilization Wrap (i.e.: the weight of the metal mass)

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Summary of Technological Characteristics

TABLE 3: Comparison of Proposed and Predicate Devices

Device Characteristic	Proposed Device	Predicate Device	Reference Devices	Comparison Analysis
Product Name	Gemini Sterilization Wrap	Gemini Sterilization Wrap	Gemini and Gemini Bonded Sterilization Wrap	Same
510(k) Reference		K150698	K152564 K152458	N/A
Product Owner	Medline Industries, Inc.	Medline Industries, Inc.	Medline Industries, Inc.	Identical
Product Code	FRG	FRG	FRG	Identical
Intended Use	Gemini Sterilization Wraps are intended to be used to enclose another medical device that is to be sterilized by a health care provider. It is intended to allow sterilization of the enclosed medical device and also to maintain sterility of such content until used.	The Gemini Single Ply and Bonded Wraps are intended to allow sterilization of the enclosed medical device(s) and also to maintain sterility of the enclosed medical device(s) within the period of time for which performance data demonstrating maintenance of sterility has been provided.	Gemini and Gemini Bonded Sterilization Wraps are intended to be used to enclose another medical device that is to be sterilized by a health care provider. It is intended to allow sterilization of the enclosed medical device and also to maintain sterility of such content until used.	Identical to K152564 and K152458. Similar to K150698.
Regulation Number	21 CFR 880.6850	21 CFR 880.6850	21 CFR 880.6850	Identical
Design Features	Square or rectangular sheets manufactured by spunbond-meltblown process	Square or rectangular sheets manufactured by spunbond-meltblown process	Square or rectangular sheets manufactured by spunbond-meltblown process	Identical
Design Configurations	12 in. x 12 in. to 54 in. x 90 in.	12 in. x 12 in. to 54 in. x 90 in.	12 in. x 12 in. to 54 in. x 90 in.	Identical
Materials	Polypropylene with phthalocyanine blue, titanium dioxide and disazocondensation red	Polypropylene with phthalocyanine blue, titanium dioxide	Polypropylene with phthalocyanine blue, titanium dioxide and disazocondensation red	Similar to K150698. Identical to K152564 and K152458.
Wrapping Technique	Sequential/simultaneous double wrapping	Sequential/simultaneous double wrapping	Sequential/simultaneous double wrapping	Identical
Bonding Material	Ultrasonically seamed in a dotted line pattern	Ultrasonically seamed in a dotted line pattern	Ultrasonically seamed in a dotted line pattern	Identical

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Prescription vs. OTC	OTC	OTC	OTC	Identical
Sterilization	Sterizone VP4 V-PRO® 60 (Lumen, Non-Lumen, Flexible) V-PRO® 1 (Lumen cycle) V-PRO® 1 Plus (Lumen, Non-Lumen) V-PRO® maX (Lumen, Non-Lumen, Flexible)	V-PRO® 1 (Lumen cycle) V-PRO® 1 Plus (Lumen, Non-Lumen) V-PRO® maX (Lumen, Non-Lumen, Flexible)	Pre-vacuum steam Gravity steam STERRAD 50, 200S and 100NX DUO Cycles	Different
Disposable vs. Non-Disposable	Disposable	Disposable	Disposable	Identical
Single Use vs. Reusable	Single Use Only	Single Use Only	Single Use Only	Identical
Maintenance of Sterility	V-PRO® 1 - 1 year* V-PRO® 1 Plus – 1 year* V-PRO® maX – 1 year* V-PRO® 60 – 1 year Sterizone VP4 – 1 year	30 days	Steam – 2 years STERRAD – 180 days	Different

*Sterilization cycles cleared in previous 510(k)'s are included here due to the additional indication for use of maintenance of sterility now being 1 year.

Summary of Non-Clinical Testing

TABLE4: Summary of Performance Testing V-PRO® 60

Performance Study	Performance Results
Maintenance of Sterility	Passed
Sterilant Penetration	Passed
Tensile breaking strength and elongation (ASTM D5034)	Passed
Tear Strength (ASTM D5587)	Passed
Hydrostatic Pressure (AATCC 127)	Passed
Burst Pressure (ASTM D3786)	Passed
Air Permeability (ASTM D737)	Passed
Post Sterilization Biocompatibility (Cytotoxicity – ISO 10993-5 Post Sterilization Biocompatibility (Primary Skin Irritation Testing- ISO 10993-10)	Passed

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TABLE 5: Summary of Performance Testing Sterizone VP4

Performance Study	Performance Results
Maintenance of Sterility	Passed
Sterilant Penetration	Passed
Tensile breaking strength and elongation (ASTM D5034)	Passed
Tear Strength (ASTM D5587)	Passed
Hydrostatic pressure (AATCC 127)	Passed
Air Permeability (ASTM D737)	Passed
Post Sterilization Biocompatibility (Cytotoxicity – ISO 10993-5 Post Sterilization Biocompatibility (Primary Skin Irritation Testing- ISO 10993-10)	Passed

Summary of Clinical Testing

Not applicable.

Conclusion

In accordance with 21 CFR Part 807, and based on the information provided in this premarket notification, Medline Industries, Inc. concludes that the Gemini Sterilization Wrap is as safe and as effective for their intended use as the predicate device Gemini Sterilization Wrap (K150698).