



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

November 20, 2015

Medline Industries, Inc.
Ms. Jennifer Mason
Senior Regulatory Affairs Specialist
1 Medline Place
Mundelein, IL 60060

Re: K150698
Trade/Device Name: Gemini Sterilization Wrap
Regulation Number: 21 CFR 880.6850
Regulation Name: Sterilization Wrap
Regulatory Class: II
Product Code: FRG
Dated: October 16, 2015
Received: October 19, 2015

Dear Ms. 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 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,

Erin I. Keith -S

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 (if known)

Device Name

Gemini Sterilization Wrap

Indications for Use (Describe)

The Gemini Single Ply and Bonded Sterilization Wraps are intended to allow sterilization of the enclosed medical devices(s) and also maintain sterility of the enclosed medical device(s) within the period of time for which performance data demonstrating maintenance of sterility has been provided.

The Gemini Single Ply and Bonded Sterilization Wraps have been validated for use with Lumen, Non Lumen, and Flexible Cycles by the STERIS Amsco® V-PRO™ 1, Amsco® V-PRO™ 1 Plus, and Amsco® V-PRO™ maX Low Temperature Sterilization Systems.

Table 1 provides a listing of validated sterilization cycles

Table 2 provides recommended weights for each wrap model

Table 3 provides maintenance of package sterility recommendations

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 – Validated STERIS Amsco® V-PRO™ Cycles

Amsco® V-PRO™ Cycle	Maximum Recommended Chamber Load	Intended Load
Lumen Cycle	19.65 lbs.	Reusable metal and non-metal medical devices, including up to 20 lumens of the following dimensions per chamber load: <ul style="list-style-type: none"> • An inside diameter of 1 mm or larger and a length of 125 mm or shorter • An inside diameter of 2 mm or larger and a length of 250 mm or shorter • An inside diameter of 3 mm or larger and a length of 400 mm or shorter
Non Lumen Cycle	19.65 lbs.	Non-lumened reusable metal and non-metal medical devices
Flexible Cycle	24 lbs.	Single or dual lumen surgical flexible endoscopes and bronchoscopes in either of two load configurations: <ol style="list-style-type: none"> 1. Two trays, each containing a flexible endoscope with a light cord (if not integral to endoscope) and mat with no additional load 2. One tray containing a flexible endoscope with a light cord (if not integral to endoscope) and mat and an additional tray containing non-lumened medical devices The flexible endoscopes(s) may contain either: <ul style="list-style-type: none"> • A single lumen with an inside diameter of 1 mm or larger and a length of 1050 mm or shorter • Two lumens, with one lumen having an inside diameter of 1 mm or larger and length of 998 mm or shorter and the other lumen having an inside diameter of 1 mm or larger and a length of 850 mm or shorter

Gemini Single Ply and Bonded Sterilization Wraps Recommendations for Use with the STERIS Amsco® V-PRO™ 1, Amsco® V-PRO™ 1 Plus, and Amsco® V-PRO™ maX Low Temperature Sterilization Systems are provided in Table 3.

Table 2 – Wrap Model Recommendations for STERIS Amsco® V-PRO™ 1, Amsco® V-PRO™ 1 Plus, and Amsco® V-PRO™ maX Low Temperature Sterilization¹

Gemini Wrap Weight	Item Number Series	Intended Load	Maximum Recommended Wrapped Package Content	Description of Loads Used in Sterility Maintenance Validation Study²
Light Weight	GEM1XXX GEM11XXS	Light Weight Package (for example: telescope with light cord)	6.5 lbs.	2.5 lbs. metal mass 6 forceps V-PRO tray (17" x 10" x 3 ½") at 4 lbs.
Regular Weight	GEM2XXX GEM21XXS	Light to Moderate Weight Package (for example: general use medical instruments)	9 lbs.	5 lbs. metal mass 6 forceps V-PRO tray (17" x 10" x 3 ½") at 4 lbs.
Medium Weight	GEM3XXX GEM31XXS	Moderate to Heavy Weight Package (for example: general use medical instruments)	10 lbs.	6 lbs. metal mass 6 forceps V-PRO tray (17" x 10" x 3 ½") at 4 lbs.
Heavyweight	GEM4XXX GEM41XXS	Heavyweight Package (for example: general use medical instruments)	10 lbs.	5 lbs. metal mass 6 forceps V-PRO tray (17" x 10" x 3 ½") at 5 lbs.
Super Heavyweight	GEM5XXX GEM51XXS	Very Heavyweight Package (for example: general use medical instruments)	10 lbs.	5 lbs. metal mass 6 forceps V-PRO tray (17" x 10" x 3 ½") at 5 lbs.

¹Individual 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.

²It 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 size of individual content types that were validated for the Gemini Single Ply and Bonded Sterilization Wraps (i.e.: the weight of the metal mass).

Table 3 - Maintenance of Package Sterility Recommendations

Models	V-PRO Cycles
Gemini Sterilization Wrap Single Play and Bonded	30 days



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510(k) SUMMARY

[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
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Summary Preparation Date

November 19, 2015

Type of 510(k) Submission

Traditional

Device Name / Classification

Name of Device: Gemini Sterilization Wrap
Proprietary Name: Gemini Sterilization Wrap
Common Name: Sterilization Wrap
Classification Name: Sterilization Wrap
Product Code: FRG
Classification Panel: General Hospital

Predicate Device

KIMGUARD ONE-STEP Sterilization Wrap
PREDICATE DEVICE K112805

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 the Gemini Sterilization Wrap ultrasonically seamed on two



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parallel sides. This allows for convenient wrapping with two sheets simultaneously. The wrap allows for aseptic opening of the sterilized package.

Gemini Sterilization Wrap items are square or rectangular sheets of 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 5 different shades of blue that vary in the amount of phthalocyanine blue pigmentation depending on the weight of the wrap. The lightest weight wrap has the least amount of blue pigment and the super heavy weight has the highest amount. Also, some wraps contain titanium dioxide and others do not.

Gemini Sterilization Wrap is available in sizes ranging from 12"x12" to 54"x72" across five different material weights/models.

Indications for Use

The Gemini Single Ply and Bonded Sterilization Wraps are intended to allow sterilization of the enclosed medical device(s) and also maintain sterility of the enclosed medical device(s) within the period of time for which performance data demonstrating maintenance of sterility has been provided.

The Gemini Single Ply and Bonded Sterilization Wraps have been validated for use with Lumen, Non Lumen, and Flexible Cycles by the STERIS Amsco® V-PRO™ 1, Amsco® V-PRO™ 1 Plus, and Amsco® V-PRO™ maX Low Temperature Sterilization Systems.

Table 1 provides a listing of validated sterilization cycles

Table 2 provides recommended weights for each wrap model

Table 3 provides maintenance of package sterility recommendations



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Amsco® V-PRO™ Cycle	Maximum Recommended Chamber Load	Intended Load
Lumen Cycle	19.65 lbs.	Reusable metal and non-metal medical devices, including up to 20 lumens of the following dimensions per chamber load: <ul style="list-style-type: none"> • An inside diameter of 1 mm or larger and a length of 125 mm or shorter • An inside diameter of 2 mm or larger and a length of 250 mm or shorter • An inside diameter of 3 mm or larger and a length of 400 mm or shorter
Non Lumen Cycle	19.65 lbs.	Non-lumened reusable metal and non-metal medical devices
Flexible Cycle	24 lbs.	Single or dual lumen surgical flexible endoscopes and bronchoscopes in either of two load configurations: <ol style="list-style-type: none"> 1. Two trays, each containing a flexible endoscope with a light cord (if not integral to endoscope) and mat with no additional load 2. One tray containing a flexible endoscope with a light cord (if not integral to endoscope) and mat and an additional tray containing non-lumened medical devices The flexible endoscopes(s) may contain either: <ul style="list-style-type: none"> • A single lumen with an inside diameter of 1 mm or larger and a length of 1050 mm or shorter • Two lumens, with one lumen having an inside diameter of 1 mm or larger and length of 998 mm or shorter and the other lumen having an inside diameter of 1 mm or larger and a length of 850 mm or shorter



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Gemini Single Ply and Bonded Sterilization Wraps Recommendations for Use with the STERIS Amsco® V-PRO™1, Amsco® V-PRO™ 1 Plus, and Amsco® V-PRO™ maX Low Temperature Sterilization systems are provided in Table 3.

Table 2 - Wrap Model Recommendations for STERIS Amsco® V-PRO™ 1, Amsco® V-PRO™ 1 Plus, and Amsco® V-PRO™ maX Low Temperature Sterilization¹

Gemini Wrap Weight	Item Number Series	Intended Load	Maximum Recommended Wrapped Package Content	Description of Loads Used in Sterility Maintenance Validation Study²
Light Weight	GEM11XX GEM11XXS	Light Weight Package (for example: telescope with light cord)	6.5 lbs.	2.5 lbs. metal mass 6 forceps V-PRO tray (17" x 10" x 3 ½") at 4 lbs.
Regular Weight	GEM21XX GEM21XXS	Light to Moderate Weight Package (for example: general use medical instruments)	9 lbs.	5 lbs. metal mass 6 forceps V-PRO tray (17" x 10" x 3 ½") at 4 lbs.
Medium Weight	GEM31XX GEM31XXS	Moderate to Heavy Weight Package (for example: general use medical instruments)	10 lbs.	6 lbs. metal mass 6 forceps V-PRO tray (17" x 10" x 3 ½") at 4 lbs.
Heavyweight	GEM41XX GEM41XXS	Heavyweight Package (for example: general use medical instruments)	10 lbs.	5 lbs. metal mass 6 forceps V-PRO tray (17" x 10" x 3 ½") at 5 lbs.
Super Heavyweight	GEM51XX GEM51XXS	Very Heavyweight Package (for example: general use medical instruments)	10 lbs.	5 lbs. metal mass 6 forceps V-PRO tray (17" x 10" x 3 ½") at 5 lbs.

¹Individual 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.



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Table 3 - Maintenance of Package Sterility Recommendations

Models	V-PRO Cycles
Gemini Sterilization Wrap Single Ply and Bonded	30 days

Summary of Technological Characteristics

Comparison of Proposed and Predicate Devices

Device Characteristic	Proposed Device	Predicate Device	Comparison Analysis
Product Name	Gemini Sterilization Wrap	KINGGUARD ONE-STEP Sterilization Wrap	
510(k) Reference		K112805	
Product Owner	Medline Industries, Inc	Kimberly Clark	
Product Code	FRG	FRG	Same
Intended Use	<p>The Gemini Single Ply and Bonded Sterilization Wraps are intended to enclose another medical device that is to be sterilized by a health care provider using:</p> <ul style="list-style-type: none"> Lumen, Non Lumen, and Flexible Cycles by the STERIS Amsco V-PRO, Amsco V-PRO 1 Plu, and amsco V-PRO maX Low Temperature Sterilization Systems. <p>The Gemini Single Ply and Bonded Sterilization Wraps are intended to allow</p>	<p>KINGGUARD ONE-STEP* Sterilization Wrap is intended to be used to enclose another medical device that is to be sterilized by a healthcare provider in the Amsco® V-PRO™ 1 Low Temperature Sterilization System’s Cycle, The Amsco® V-PRO™ 1 Plus Low Temperature Sterilization System’s Lumen (Identical to the V-PRO™ 1 Cycle), and Non Lumen Cycles, and The V-PRO™ Low Temperature Sterilization System’s Flexible Cycle. The wrap is intended to maintain sterility of the enclosed device(s) until opened within the period of time for which performance data demonstrating maintenance of sterility has been provided.</p>	Similar



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	sterilization of the enclosed medical device(s) and also maintain sterility of the enclosed device(s) until used, which complies with 21 CFR 880.6850. “A sterilization wrap (pack, sterilization wrapper, bag, or accessories) is a device intended to be used to enclose another medical device that is to be sterilized by a healthcare provider. It is intended to allow sterilization of the enclosed medical device and also to maintain sterility of the enclosed device until used.”		
Regulation Number	21 CFR 880.6850	21 CFR 880.6850	Same
Design Features	Single Ply and Bonded with an ultrasonic seam	Bonded with an ultrasonic seam	Similar
Sizes	12”x12” to 54”x72”	12”x12” to 54”x72”	Same
Materials	Polypropylene Spunbond-Spunbond-meltblown-meltblown-spunbond nonwoven fabric	Polypropylene Spunbond-meltblown-spunbond (SMS) Trilaminate nonwoven fabric	Similar
Prescription vs. OTC	OTC	OTC	Same
Sterilization	Lumen, Non Lumen, and Flexible Cycles by the STERIS Amsco V-PRO1, AMSCO V-PRO 1 Plus, and Amsco V-PRO maX Low Temperature Sterilization Systems	Lumen, Non Lumen, and Flexible Cycle in the Amsco V-Pro 1, Amsco V-PRO 1 Plus, and Amsco V-PRO maX Low Temperature Sterilization Systems	Same
Wrapping Technique	Sequential/simultaneous double wrapping	Simultaneous double wrapping	Similar
Disposable vs. Non-Disposable	Disposable	Disposable	Same



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Single Use vs. Reusable	Single Use	Single Use	Same
Biocompatibility Testing	Pass	Pass	Same
Event Related Maintenance of Package Sterility	Pass	Pass	Same

Summary of Non-Clinical Testing

Biocompatibility Testing

The biocompatibility evaluation for Gemini Sterilization Wrap was conducted in accordance with ANSI/AAMI/ISO 10993-1:2009 *Biological Evaluation of Medical Devices—Part 1: Evaluation and Testing Within a Risk Management Process*, as recognized by FDA. Gemini Sterilization Wrap is classified as non-patient contacting devices. Specific biocompatibility tests were selected under the guidance of ISO 10993-1:2009 Annex A.

The following tests were performed to evaluate the biocompatibility of Gemini Sterilization Wrap:

- ISO 10993-10: Irritation – Intracutaneous reactivity; and
- ISO 10993-10: Delayed-Type Hypersensitivity (Sensitization) – Guinea Pig Maximization Test

A study was performed on the Gemini Sterilization Wrap by analysis of semi-volatile to non-volatile and elemental leachables utilizing inductively coupled plasma-mass spectrometry (ICP-MS) and high-performance liquid chromatography (HPLC-MS).

Performance Testing (Bench)

Medline Gemini Wraps were evaluated through a series of performance tests including tensile breaking strength and elongation (ASTM D5034), tearing strength (ASTM D5587), hydrostatic pressure (AATCC 127), and air permeability (ASTM D737).

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 Wraps are as safe and as effective and substantially equivalent to the predicate KIMGUARD ONE-STEP Sterilization Wrap (K112805)] as described herein.