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 1, 2016

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

Re: K152458
Trade/Device Name: Gemini Bonded Sterilization Wrap
Regulation Number: 21 CFR 880.6850
Regulation Name: Sterilization wrap
Regulatory Class: Class II
Product Code: FRG
Dated: May 4, 2016
Received: May 5, 2016

Dear Ms. 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" (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 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 yours,

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

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)*
K152458

Device Name
Gemini Bonded Sterilization Wrap

Indications for Use *(Describe)*
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. Gemini Bonded Sterilization Wrap is validated for use in steam or STERRAD sterilization processes in the following sterilization 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: Pre-vacuum team at 270°F/132°C for 4 minutes with the following dry times by weight

Gemini Wrap Model	Gemini Wrap Weight	Dry Time
GEM11XXS / GEM11XXT	Lightweight	20 Minutes
GEM21XXS / GEM21XXT	Regular Weight	20 Minutes
GEM31XXS / GEM31XXT	Medium Weight	20 Minutes
GEM41XXS / GEM41XXT	Heavyweight	30 Minutes
GEM51XXS / GEM51XXT	Super Heavyweight	30 Minutes

TABLE 2: Gravity steam at 250°F/121°C for 30 minutes with the following dry times by weight

Gemini Wrap Model	Gemini Wrap Weight	Dry Time
GEM11XXS / GEM11XXT	Lightweight	20 Minutes
GEM21XXS / GEM21XXT	Regular Weight	20 Minutes
GEM31XXS / GEM31XXT	Medium Weight	20 Minutes
GEM41XXS / GEM41XXT	Heavyweight	30 Minutes
GEM51XXS / GEM51XXT	Super Heavyweight	30 Minutes

TABLE 3: STERRAD® Sterilization

Gemini Wrap Model	Gemini Wrap Weight	STERRAD® Cycles
GEM11XXS / GEM11XXT	Lightweight	STERRAD® 50, 200S and 100NX™ DUO Cycles
GEM21XXS / GEM21XXT	Regular Weight	STERRAD® 50, 200S and 100NX™ DUO Cycles
GEM31XXS / GEM31XXT	Medium Weight	STERRAD® 50, 200S and 100NX™ DUO Cycles
GEM41XXS / GEM41XXT	Heavyweight	STERRAD® 50, 200S and 100NX™ DUO Cycles
GEM51XXS / GEM51XXT	Super Heavyweight	STERRAD® 50, 200S and 100NX™ DUO Cycles

The Gemini Bonded Sterilization Wrap intended loads with pre-vacuum steam sterilization, gravity steam sterilization and the Advanced Sterilization Products STERRAD® Sterilization systems are provided in Table 4.

The Gemini Bonded Sterilization Wrap Recommendations for use with Pre-vacuum steam cycles, Gravity steam cycles, and the Advanced Sterilization Products STERRAD® Sterilization systems are provided in Table 5.

TABLE 4: Validated Pre-Vacuum Steam, Gravity Steam, and Advanced Sterilization Products STERRAD® 50, 200S and STERRAD® 100 NX™ Cycles

Cycle	Maximum recommended Chamber Load		Intended Load
Pre-Vacuum Steam & Gravity Steam Cycles	Lightweight	6 lbs.	2 huck towels (17 in. x 29 in.), 3 fluid-resistant drapes (108 in. x 72 in.)
	Regular Weight	9 lbs.	16 huck towels (17 in. x 29 in.), 1 fluid resistant table cover (90 in. x 60 in.). 5 lbs. of metal mass.
	Medium Weight	13 lbs.	4 tray liners (20 in. x 25 in.) stacked 23 in. x 11 in. x 3.5 in. tray containing 11 lbs. of metal mass.

	Heavyweight	17 lbs.	4 tray liners (20 in. x 25 in.) stacked 23 in. x 11 in. x 3.5 in. tray containing 15 lbs. of metal mass.
	Super Heavyweight	25 lbs.	4 tray liners (20 in. x 25 in.) stacked 23in. x 11in. x 3.5 in. tray containing 20 lbs. of metal mass.
STERRAD® 50	10.7 lbs.		Reusable metal and non-metal medical devices, including up to 10 lumens of the following dimensions per chamber load: • An inside diameter of 1mm or larger and a length of 125 mm or shorter of single-channel stainless steel lumens. • An inside diameter of 2 mm or larger and a length of 250 mm or shorter of single-channel stainless steel lumens. • An inside diameter of 3mm or larger and length of 400 mm or shorter of single-channel stainless steel lumens • An inside diameter of 6 mm or larger and a length of 310 mm or shorter of single-channel Teflon-Polyethylene lumens. • Refer to the STERRAD® 50 Sterilizer User's Guide for complete instructions on load(s) and cycle(s), including chamber loading instructions (i.e., 10 lumens per load).
STERRAD® 200S	10.7 lbs.		Reusable metal and non-metal medical devices, including up to 12 lumens of the following dimensions per chamber load: • An inside diameter of 1mm or larger and a length of 125 mm or shorter of single-channel stainless steel lumens. • An inside diameter of 2 mm or larger and a length of 250 mm or shorter of single-channel stainless steel lumens. • An inside diameter of 3mm or larger and length of 400 mm or shorter of single-channel stainless steel lumens • An inside diameter of 6 mm or larger and a length of 310 mm or shorter of single-channel Teflon-Polyethylene lumens. Refer to the STERRAD® 200 Sterilizer User's Guide for complete instructions on load(s) and cycle(s), including chamber loading instructions (i.e., 36.48 lbs. per load).
STERRAD® 100NX™ DUO cycle	10.7 lbs.		One or two single-channel Flexible Endoscope with accessory devices that are normally connected to it, with or without a silicone mat. The flexible endoscope may contain: • A single-channel Teflon®/Polyethylene lumen with an inside diameter of 1 mm or larger and a length of 850 mm or shorter. • Accessory devices that are normally connected to a flexible endoscope during use. • Flexible endoscopes without lumens. Refer to the STERRAD® 100NX™ Sterilizer User's Guide for

		complete instructions on load(s) and cycle(s), including chamber loading instructions (i.e., 13.2 lbs. per load).

TABLE 5: Wrap Model Recommendations for Use with Pre-vacuum steam cycles, Gravity steam cycles, and the Advanced Sterilization Products STERRAD® Sterilization Systems

Gemini Wrap Weight	Gemini Wrap Model	Intended Load	Maximum Recommended Wrapped Package Content[2]	
			Pre-Vacuum, Gravity, and EO	ASP STERRAD® 50, 200S and 100NX™ Cycles
Light Weight	GEM11XX	Light weight package (for example: standard linen packs)	6 lbs.	10.7 lbs.
Regular Weight	GEM21XX	Light to moderate weight package (for example: general use medical instruments)	9 lbs.	10.7 lbs.
Medium Weight	GEM31XX	Moderate to heavy weight package (for example: general use medical instruments)	13 lbs.	10.7 lbs.
Heavy Weight	GEM41XX	Heavy weight package (for example: general use medical instruments)	17 lbs.	10.7 lbs.
Super Heavy Weight	GEM51XX	Very heavy weight package (for example: general use medical instruments)	25 lbs.	10.7 lbs.

[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 size of individual content types that were validated for the Gemini Bonded Sterilization Wraps (i.e.: the weight of the metal mass).

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

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

K152458

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
May 4, 2016

Type of 510(k) Submission
Traditional

Device Name / Classification
Name of Device: Gemini Bonded Sterilization Wrap
Proprietary Name: Gemini Bonded Sterilization Wrap
Common Name: Sterilization Wrap
Classification Name: Wrap, Sterilization
Product Code: FRG
Classification: 21 CFR 880.6850
Device Class: Class II
Classification Panel: General Hospital

Predicate Device
Gemini Bonded Sterilization Wrap
K143147

Device Description
There have been no changes to the Gemini Bonded Sterilization Wrap. The materials of construction, colorants, sizes and product specifications have not changed and are identical to what was cleared under K143147.

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

As previously described in K143147, Gemini Bonded Sterilization Wrap is offered to the marketplace as bulk packages of two ply sheets which are ultrasonically bonded together for use by customers in accordance with standard hospital practices which require that two sheets are used each time a medical device or collection of medical devices are wrapped. The Gemini Bonded Sterilization Wrap provides the protection of double-wrapping in an efficient manner; cutting wrap/unwrap time in half, compared to traditional double-wrapping methods.

Gemini Bonded Sterilization Wrap 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 wrap allows for aseptic opening of the sterilized package.

The two-tone blue/pink wrap fabric is made of polypropylene with the addition of less than 2% of phthalocyanine blue pigmentation, less than 0.5% of titanium dioxide white pigmentation and less than 2% of disazocondensation red pigmentation. The wrap allows for aseptic opening of the sterilized package.

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

Indications for Use

Gemini Bonded Sterilization Wrap is 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 steam or STERRAD® sterilization processes in the following sterilization modes and cycles:

TABLE 1: Pre-vacuum steam at 270°F/132°C for 4 minutes with the following dry times by weight

Gemini Wrap Model	Gemini Wrap Weight	Dry Time
GEM11XXS / GEM11XXT	Lightweight	20 Minutes
GEM21XXS / GEM21XXT	Regular Weight	20 Minutes
GEM31XXS / GEM31XXT	Medium Weight	20 Minutes
GEM41XXS / GEM41XXT	Heavyweight	30 Minutes
GEM51XXS / GEM51XXT	Super Heavyweight	30 Minutes

TABLE 2: Gravity steam at 250°F/121°C for 30 minutes with the following dry times by weight

Gemini Wrap Model	Gemini Wrap Weight	Dry Time
GEM11XXS / GEM11XXT	Lightweight	20 Minutes
GEM21XXS / GEM21XXT	Regular Weight	20 Minutes
GEM31XXS / GEM31XXT	Medium Weight	20 Minutes
GEM41XXS / GEM41XXT	Heavyweight	30 Minutes
GEM51XXS / GEM51XXT	Super Heavyweight	30 Minutes

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

TABLE 3: STERRAD® Sterilization

Gemini Wrap Model	Gemini Wrap Weight	STERRAD® Cycles
GEM11XXS / GEM11XXT	Lightweight	STERRAD® 50, 200S and 100NX™ Cycles
GEM21XXS / GEM21XXT	Regular Weight	STERRAD® 50, 200S and 100NX™ Cycles
GEM31XXS / GEM31XXT	Medium Weight	STERRAD® 50, 200S and 100NX™ Cycles
GEM41XXS / GEM41XXT	Heavyweight	STERRAD® 50, 200S and 100NX™ Cycles
GEM51XXS / GEM51XXT	Super Heavyweight	STERRAD® 50, 200S and 100NX™ Cycles

The Gemini Bonded Sterilization Wrap intended loads with pre-vacuum steam sterilization, gravity steam sterilization and the Advanced Sterilization Products STERRAD® Sterilization systems are provided in Table 4.

The Gemini Bonded Sterilization Wrap Recommendations for use with Pre-vacuum steam cycles, Gravity steam cycles, and the Advanced Sterilization Products STERRAD® Sterilization systems are provided in Table 5.

TABLE 4: Validated Pre-Vacuum Steam, Gravity Steam, and Advanced Sterilization Products STERRAD® 50, 200S, 100NX™ DUO Cycles

Cycle	Maximum recommended Chamber Load		Intended Load
Pre-Vacuum Steam & Gravity Steam Cycles	Lightweight	6 lbs.	2 huck towels (17 in. x 29 in.), 3 fluid-resistant drapes (108 in. x 72 in.)
	Regular Weight	9 lbs.	16 huck towels (17 in. x 29 in.), 1 fluid resistant table cover (90 in. x 60 in.). 5 lbs. of metal mass.
	Medium Weight	13 lbs.	4 tray liners (20 in. x 25 in.) stacked 23 in. x 11 in. x 3.5 in. tray containing 11 lbs. of metal mass.
	Heavyweight	17 lbs.	4 tray liners (20 in. x 25 in.) stacked 23 in. x 11 in. x 3.5 in. tray containing 15 lbs. of metal mass.
	Super Heavyweight	25 lbs.	4 tray liners (20 in. x 25 in.) stacked 23in. x 11in. x 3.5 in. tray containing 20 lbs. of metal mass.
STERRAD® 50	10.7 lbs.		Reusable metal and non-metal medical devices, including up to 10 lumens of the following dimensions per chamber load: • An inside diameter of 1mm or larger and a length of 125 mm or shorter of single-channel stainless steel lumens. • An inside diameter of 2 mm or larger and a length of 250 mm or shorter of single-channel stainless steel lumens.

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One Medline Place
Mundelein, IL 60060

		• An inside diameter of 3mm or larger and length of 400 mm or shorter of single-channel stainless steel lumens • An inside diameter of 6 mm or larger and a length of 310 mm or shorter of single-channel Teflon-Polyethylene lumens. • Refer to the STERRAD® 50 Sterilizer User's Guide for complete instructions on load(s) and cycle(s), including chamber loading instructions (i.e., 10 lumens per load).
STERRAD® 200 S	10.7 lbs.	Reusable metal and non-metal medical devices, including up to 12 lumens of the following dimensions per chamber load: • An inside diameter of 1mm or larger and a length of 125 mm or shorter of single-channel stainless steel lumens. • An inside diameter of 2 mm or larger and a length of 250 mm or shorter of single-channel stainless steel lumens. • An inside diameter of 3mm or larger and length of 400 mm or shorter of single-channel stainless steel lumens • An inside diameter of 6 mm or larger and a length of 310 mm or shorter of single-channel Teflon-Polyethylene lumens. Refer to the STERRAD® 200 Sterilizer User's Guide for complete instructions on load(s) and cycle(s), including chamber loading instructions (i.e., 36.48 lbs. per load).
STERRAD® 100NX™ DUO cycle	10.7 lbs.	One or two single-channel Flexible Endoscope with accessory devices that are normally connected to it, with or without a silicone mat. The flexible endoscope may contain: • A single-channel Teflon®/Polyethylene lumen with an inside diameter of 1 mm or larger and a length of 850 mm or shorter. • Accessory devices that are normally connected to a flexible endoscope during use. • Flexible endoscopes without lumens. Refer to the STERRAD® 100NX™ Sterilizer User's Guide for complete instructions on load(s) and cycle(s), including chamber loading instructions (i.e., 13.2 lbs. per load).

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

TABLE 5: Wrap Model Recommendations for Use with Pre-vacuum steam cycles, Gravity steam cycles, and the Advanced Sterilization Products STERRAD® Sterilization Systems

Gemini Wrap Weight	Gemini Wrap Model	Intended Load	Maximum Recommended Wrapped Package Content[2]	
			Pre-Vacuum, Gravity, and EO	ASP STERRAD® 50, 200S and 100NX™ Cycles
Light Weight	GEM11XX	Light weight package (for example: standard linen packs)	6 lbs.	10.7 lbs.
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Medium Weight	GEM31XX	Moderate to heavy weight package (for example: general use medical instruments)	13 lbs.	10.7 lbs.
Heavy Weight	GEM41XX	Heavy weight package (for example: general use medical instruments)	17 lbs.	10.7 lbs.
Super Heavy Weight	GEM51XX	Very heavy weight package (for example: general use medical instruments)	25 lbs.	10.7 lbs.

[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 size of individual content types that were validated for the Gemini Bonded Sterilization Wraps (i.e.: the weight of the metal mass).

Maintenance of Sterility (Shelf Life)

Validation performance data for the Gemini Bonded Sterilization Wrap is listed below in Table 6.

TABLE 6: Maintenance of Sterility

Sterilization Modality	Shelf Life
Pre-Vacuum & Gravity Steam	2 years
STERRAD® 50, 200S and 100NX™ Cycles	180 days

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

Summary of Technological Characteristics

TABLE 7: COMPARISON OF PROPOSED AND PREDICATE DEVICES

Device Characteristic	Proposed Device	Predicate Device	Comparison Analysis
Product Name	Gemini Bonded Sterilization Wrap	Gemini Bonded Sterilization Wrap	Same
510(k) Reference		K143147	
Product Owner	Medline Industries, Inc.	Medline Industries, Inc.	Same
Product Code	FRG	FRG	Same
Intended Use	Gemini Bonded Sterilization Wrap is 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.	Gemini Bonded Sterilization Wrap is 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.	Same
Regulation Number	21 CFR 880.6850	21 CFF 880.6850	Same
Design Features	Square or rectangular sheets mfd. by spunbond-meltblown process	Square or rectangular sheets mfd. by spunbond-meltblown process	Same
Design Configurations	12 in. x 12 in. to 54 in. x 90 in.	12 in. x 12 in. to 54 in. x 90 in.	Same
Materials	Polypropylene with phthalocyanine blue, titanium dioxide and disazocondensation red	Polypropylene with phthalocyanine blue, titanium dioxide and disazocondensation red	Same
Wrapping Technique	Sequential/simultaneous double wrapping	Sequential/simultaneous double wrapping	Same
Bonding Material	Ultrasonically seamed in a dotted line pattern along two sides	Ultrasonically seamed in a dotted line pattern along two sides	Same
Prescription vs. OTC	OTC	OTC	Same
Sterilization	Pre-Vacuum Steam Cycle: 4 Minutes Exposure at 270°F/132C° with minimum 20 minutes dry time	Pre-Vacuum Steam Cycle: 4 Minutes Exposure at 270°F/132C° with minimum 20 minutes dry time	Same
	Gravity Steam Cycle: 30 Minutes Exposure at 250°F/121°C with minimum	Gravity Steam Cycle: 30 Minutes Exposure at 250°F/121°C with minimum	Same

	20 minutes dry time	20 minutes dry time	
	STERRAD® 50, 200S and 100NX™ DUO	N/A	Different
	STERRAD® NX™, (Standard Cycle, Advanced Cycle)	STERRAD® NX™, (Standard Cycle, Advanced Cycle)	Same
	STERRAD® 100S, Standard Cycle	STERRAD® 100S, Standard Cycle	Same
	STERRAD® 100NX™, (Standard Cycle, Flex Cycle, EXPRESS Cycle)	STERRAD® 100NX™, (Standard Cycle, Flex Cycle, EXPRESS Cycle)	Same
Maintenance of Sterility (Shelf Life)	Steam – 2 years	Steam – 180 days	Different
	STERRAD® – 180 days	STERRAD® – 180 days	Same
Single Use vs. Reusable	Single Use	Single Use	Same

Discussion of Similarities and Differences

The proposed Gemini Bonded Sterilization Wrap is substantially equivalent in intended use, materials, device features / specifications and function in comparison to the predicate (K143147) Gemini Bonded Sterilization Wrap. As noted in the table above, these characteristic comparisons render the devices identical. The difference between subject/predicate devices is related to:

- Maintenance of Sterility (Shelf Life): Extending the maintenance of sterility from 180 days to two years for steam sterilization based on real time stability studies. The completed stability studies were identical to the in-process stability studies described within K143147.
- Addition of STERRAD® Systems: STERRAD® 50 Cycle, STERRAD® 200S Cycle and STERRAD® 100NX™ Duo Cycle.

This product modification involving the subject and predicate devices does not significantly alter the Gemini Bonded Sterilization Wrap or raise questions regarding safety or effectiveness.

Information within this Premarket Notification demonstrates that there are no significant differences in technological characteristics between Medline's Gemini Bonded Sterilization Wrap and the cited predicate device K143147.

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

Summary of Non-Clinical Testing

TABLE 8: Summary of Performance Testing

Study		Performance Results
Maintenance of Sterility (Package integrity)	Steam Pre-Vacuum & Steam Gravity Cycles (Real Time Event Related Two Years Shelf Life)	Passed
	STERRAD® (Real Time Event Related 180 Days Shelf Life)	Passed
Pre-Vacuum Steam and Gravity Sterilant Penetration		Passed
STERRAD® 50 Cycle, STERRAD® 200S Cycle and STERRAD® 100NX™ DUO Cycle) Sterilant Penetration		Passed
Post Sterilization Biocompatibility Testing (Primary Skin Irritation Testing - ISO 10993-10)		Passed

The following performance testing was conducted on the lightest weight and the heaviest weight Gemini Bonded Sterilization Wrap both pre-sterilization and after exposure to a STERRAD 100NX cycle.

Air permeability – per ASTM D737-04 R2012
Basis weight – per ASTM D3776
Material burst strength – per ASTM D3786
Resistance to water penetration – per AATCC127
Tensile strength and elongation – per ASTM D5034
Tear strength – per ASTM D5587

The safety and effectiveness of Medline's Gemini Bonded Sterilization Wrap is adequately supported by the substantial equivalence information, materials information, and Design Control activities referenced within this Premarket Notification.

Summary of Clinical Testing

Not applicable.

Conclusion

Based on the intended use, technological characteristics, performance data, and nonclinical tests performed, the subject Gemini Bonded Sterilization Wrap are substantially equivalent to, and are as safe and as effective as, the legally marketed predicate device, Gemini Bonded Sterilization Wrap cleared under K143147.