January 24, 2020

Medline Industries, Inc.
Jennifer Mason
Senior Regulatory Affairs Specialist
Three Lakes Drive
Northfield, Illinois 60093

Re: K192641
Trade/Device Name: Gemini Titan Sterilization Wrap
Regulation Number: 21 CFR 880.6850
Regulation Name: Sterilization Wrap
Regulatory Class: Class II
Product Code: FRG
Dated: December 23, 2019
Received: December 26, 2019

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for

devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

For Sreekanth Gutala, Ph.D.
Acting Assistant Director
DHT4B: Division of Infection Control
and Plastic Surgery Devices
OHT4: Office of Surgical
and Infection Control Devices
Office of Product Evaluation and Quality
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K192641

Device Name
Gemini Titan Sterilization Wrap

Indications for Use *(Describe)*
Gemini Titan 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 the enclosed device until used.

-Pre-vacuum steam at 270°F/132°C for 4 minutes. The wrap was validated for a dry time of 30 minutes. Gemini® Titan™ Sterilization Wrap is available in square sheets ranging from 36" x 36" to 54" x 54" and can be used with trays weighing up to 25 lbs.

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

TABLE 1: Wrap Model Recommendations[1]

Wrap Weight	Gemini Wrap Model	Sterilization Cycle	Wrap Model Recommendations [1]	
			Intended Load	Maximum Recommended Wrapped Package Content
Titan Weight	GEMTITANXXT	Pre-vacuum steam at 270°F/132ºC for 4 minutes with 30 minute dry time	Very heavy weight packages (for example: large orthopedic sets)	25 lbs.

The following loads were used in the pre-vacuum steam sterilization Sterility Maintenance Validation Study:

Titan Weight: 5 lb Sterilization Tray (22.8 in. x 11.1. in. x 3.8 in.) was loaded with evenly dispersed instruments and additional medical devices throughout to achieve a total combined weight, with load and wrap, of twenty-five (25) pounds.

[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.

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 Titan Sterilization Wrap.

Medline Industries, Inc.
Three Lakes Drive
Northfield, IL 60093

K192641
510(k) SUMMARY
[AS REQUIRED BY 21CFR 807.92]

Submitter / 510(k) Sponsor
Medline Industries, Inc.
Three Lakes Drive
Northfield, IL 60093

Registration Number: 1417592

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

Summary Preparation Date
January 24, 2020

Type of 510(k) Submission
Traditional

Device Name / Classification
Name of Device: Gemini® Titan Sterilization™ Wrap
Proprietary Name: Gemini® Titan Sterilization™ Wrap
Common Name: Sterilization Wrap
Classification Name: Wrap, Sterilization
Product Code: FRG
Classification Panel: General Hospital
Regulatory Class: Class II
Regulation #: 21 CFR 880.6850

Predicate Device
Gemini® Bonded Sterilization Wrap
K152458

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Northfield, IL 60093

Device Description

Gemini® Titan™ Sterilization Wrap is offered to the market place as bulk, non-sterile packages of two ply bonded sheets of wrap. The bonded wrap is comprised of two sheets of Gemini® Titan™ Sterilization Wrap ultrasonically seamed on two parallel sides. This allows for convenient wrapping with two sheets simultaneously. Gemini® Titan™ is used to wrap a medical device or a collection of medical devices for sterilization.

The two tone wrap is comprised of a blue sheet bonded to a pink sheet. The fabric is made of polypropylene with the addition of less than 1% blue to pink color pigmentation.

Gemini® Titan™ Sterilization Wrap is available in square sheets ranging from 36” x 36” to 54” x 54” and can be used with trays weighing up to 25 lbs.

Indications for Use

Gemini® Titan™ 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.

-Pre-vacuum steam at 270°F/132°C for 4 minutes. The wrap was validated for a dry time of 30 minutes.

Summary of Technological Characteristics

TABLE 1: COMPARISON OF PROPOSED AND PREDICATE DEVICES

Device Characteristic	Proposed Device	Predicate Device	Comparison Analysis
Product Name	Gemini® Titan™ Sterilization Wrap	Gemini® Bonded Sterilization Wrap	Same
510(k) Reference	K192641	K152458	N/A
Product Owner	Medline Industries, Inc.	Medline Industries, Inc.	Same
Product Code	FRG	FRG	Same
Intended Use	Gemini Titan 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 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 under used.	Same
Regulation Number	21 CFR 880.6850	21 CFR 880.6850	Same

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Design Features	Square sheets manufactured by spunbond-meltblown process	Square or rectangular sheets manufactured by spunbond-meltblown process	Similar
Design Configurations	36 in. x 36 in. to 54 in. x 54 in.	12 in. x 12 in. to 54 in. x 90 in.	Similar
Device Weight	120 gsm	47 gsm, 54 gsm, 61 gsm, 71 gsm, and 75 gsm	Different
Materials	Polypropylene with pigment red, titanium dioxide, phthalein cyanine, permanent violet, carbon black colorants	Polypropylene with phthalocyanine blue, titanium dioxide and disazocondensation red	Different
Wrapping Technique	Sequential/simultaneous double wrapping	Sequential/simultaneous double wrapping	Same
Bonding Material	Ultrasonically seamed in a dotted line pattern	Ultrasonically seamed in a dotted line pattern	Same
Sterilization	Pre-vacuum steam	Pre-vacuum steam Gravity steam STERRAD 50, 200S and 100 NX DUO Cycles	Same
Disposable vs. Non-Disposable	Disposable	Disposable	Same
Single Use vs. Reusable	Single Use Only	Single Use Only	Same
Maintenance of Sterility	Steam – 2 years	Steam – 2 years STERRAD – 180 days	Different

Summary of Non-Clinical Testing

Sterilization efficacy, maintenance of sterility, physical properties and biocompatibility testing was conducted on the Gemini® Titan™ Sterilization Wrap to demonstrate that the product meets its intended use.

Title	Purpose	Acceptance Criteria	Results
Sterilization Efficacy	To validate the sterilization efficacy of the Gemini Titan Sterilization Wrap when processed in a steam pre-vacuum cycle of 132°C (270°F) for four minutes.	All biological indicator test samples shall be negative for growth following the minimum incubation period.	All biological indicator test samples were negative for growth. Results from the testing conclude that the Gemini Titan can achieve a 10^{-6} SAL after processing in a steam pre-vacuum sterilization cycle at 132°C (270°F) for 4 minutes.
Maintenance of Sterility (Microbial Aerosol Challenge)	To determine the microbial barrier properties of the Gemini Titan Sterilization wrap in maintaining sterility package integrity following an aerosol challenge test.	Each wrapped tray will meet the sterility maintenance requirement if there is no growth in any of the culture tubes containing the stainless-steel test coupons at	Each wrapped tray met the sterility maintenance requirement since there was no growth in any of the culture tubes containing the stainless-steel test coupons.

		the end of the incubation period.	
Biocompatibility	To determine the potential biological reactivity of a mammalian cell culture (L929) in response to the test article extract.	Acceptance criteria as specified in ISO 10993-5 Biological Evaluation of Medical Devices – Part 5: Tests for In Vitro Cytotoxicity.	There was no biological reactivity (Grade 0) of the cells exposed to the test article extract. Based on the criteria of the protocol and the ISO 10993-5 guidelines, the test article meets the requirements of the test and is not considered to have a cytotoxic effect.
	To determine the potential irritation effects of the test article extract as a result of an intracutaneous injection in New Zealand White Rabbits.	Acceptance criteria as specified in ISO 10993-10 Biological Evaluation of Medical Devices –Part 10 Tests for Irritation and Skin Sensitization.	The test article sites did not show a significantly greater biological reaction than the sites injected with the control article. Based on the criteria of the protocol, the test article meets the requirements of the ISO 10993-10 guidelines.
	To determine the potential allergenic or sensitizing capacity of the test article.	Acceptance criteria as specified in ISO 10993-10 Biological Evaluation of Medical Devices –Part 10 Tests for Irritation and Skin Sensitization.	The USP 0.9% sodium chloride for injection and cotton seed oil extracts of the test article elicited no reaction at the challenge, following an induction phase. Therefore, as defined by the grading scale of the USP, the test article is classified as a non-sensitizer.
Physical Properties	To evaluate the resistance of the material to the penetration of water under hydrostatic pressure.	Acceptance criteria as defined by AATCC 127-18 Water Resistance: Hydrostatic Pressure Test.	The processed and unprocessed Gemini Titan Sterilization Wrap met the average hydrostatic pressure acceptance criteria when tested per AATCC 127.
	To evaluate the basis weight of Gemini Titan Sterilization Wrap.	Acceptance criteria as defined by ASTM D3776/D3776M Standard Test Methods for Mass Per Unit Area (Weight) of Fabric.	The average basis weight of the processed and unprocessed Gemini Titan Sterilization Wrap met the acceptance criteria when tested per ASTM D3776/D3776M.
	The bursting strength of Gemini Titan was evaluated using a pneumatic burst tester.	Acceptance criteria as defined by ASTM D3786/D3786M-18 Standard Test Method for Bursting Strength of Textile Fabrics –	The average bursting pressure of the processed and unprocessed Gemini Titan Sterilization Wrap met the acceptance criteria when

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		Diaphragm Bursting Strength Tester Method.	tested per ASTM D3786/D3786M.
	Testing was performed per the "Grab" tensile method with specimens evaluated for their Load at Break and % Elongation at Break.	Acceptance criteria as defined by ASTM D5034-09 Standard Test Method for Breaking Strength and Elongation of Textile Fabrics (Grab Test).	When tested for machine direction and cross-machine direction, the processed and unprocessed Gemini Titan Sterilization Wrap met the average load at break when tested per ASTM D5034.
	Testing was performed to evaluate the Peak and Average Tear Forces using the trapezoid procedure.	Acceptance criteria as defined by ASTM D5587-15 Standard Test Method for Tearing Strength of Fabrics by Trapezoid Procedure.	When tested for machine direction and cross-machine direction, the processed and unprocessed Gemini Titan Sterilization Wrap met the average peak tear force acceptance criteria when tested per ASTM D5587.
	Testing to evaluate the air permeability of the Gemini Titan Sterilization Wrap.	Acceptance criteria as defined by ASTM D737 Standard Test Method for Air Permeability of Textile Fabrics.	Both the processed and unprocessed Gemini Titan Sterilization Wrap met the acceptance criteria for air permeability when tested per ASTM D737.

Summary of Clinical Testing

This section does not apply. No clinical testing was performed.

Conclusion

The conclusions drawn from the nonclinical (and clinical) tests demonstrate that the Gemini® Titan™ Sterilization Wrap is as safe, as effective, and performs as well as or better than the legally marketed device.