DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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August 25, 2017

Standard Textile Co., Inc.
% Jonathan Kahan
Partner
Hogan Lovells US LLP
555 Thirteenth Street, NW
Washington, District of Columbia 20004-1109

Re: K172207
Trade/Device Name: Standard Supreme Sterilization Wrapper
Regulation Number: 21 CFR 880.6850
Regulation Name: Sterilization Wrap
Regulatory Class: Class II
Product Code: FRG
Dated: July 21, 2017
Received: July 21, 2017

Dear Jonathan Kahan:

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 (DICE) 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 (DICE) 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,

Tara A. Ryan -S

Lori 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 on last page

510(k) Number *(if known)*

K172207

Device Name

Standard Supreme Sterilization Wrappers

Indications for Use *(Describe)*

Standard Supreme Sterilization Wrappers are intended to be used to enclose another medical device that is to be sterilized by a health care provider. They are intended to allow sterilization of the enclosed medical device and also to maintain sterility of the enclosed device until used.

Standard Supreme Sterilization Wrappers will function as a sterilization wrap when processed according to instructions. Standard Supreme Sterilization Wrappers are reusable through 75 wash, dry, and sterilization cycles. They are manufactured and distributed as non-sterile sterilization wraps that are intended to be sterilized and processed by health care facilities and/or contract sterilization/laundry companies.

Pack Assembly:
Pack assembly should follow established folding, assembly and wrapping procedures as defined by the clinical staff for aseptic presentation of the pack and its contents. The oblong and envelope folds have been validated for use on textile packs. Closure can include autoclave tape and elastomer closures.

Sterilization:
A prevacuum steam sterilization cycle (4 minute exposure at 270°F) has been validated for use on textile packs. The maximum pack size validated for use was 0.58 cubic feet with a pack weight of 12.9 pounds – pack density of 22.4 lbs./cu.ft. The maximum chamber loading configuration included 85.6 pounds of packs in a 9.1 cubic foot chamber – load density of 10.4 lbs./cu.ft.

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Table 1:
Standard Supreme Sterilization Wrappers Color and Model #'s

Sizes	Misty	Jade	Ceil
12"x12"	21520502	--	--
18"x18"	21521502	21531502	21541502
23"x23"	21522002	21532002	21542002
27"x27"	--	21532302	--
30"x30"	21522802	21532802	21542802
35"x35"	21523002	21533002	21543002
45"x45"	21525002	21535002	21545002
54"x54"	21526002	21536002	21546002
54"x72"	21528202	21538202	21548202
70"x70"	21528802	21538802	21548802

Type of Use *(Select one or both, as applicable)*

☐ Prescription Use (Part 21 CFR 801 Subpart D) X Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510K SUMMARY
STANDARD SUPREME STERILIZATION WRAPPERS (K172207)

Contact Information

Standard Textile Co., Inc.
One Knollcrest Drive
Cincinnati, Ohio 45237

Contact Person: Brad Bushman
Phone (513) 761-9255 Ext 2455; Fax (513) 679-8389
Summary Prepared on 8/24/2017

Device Information

Device Name:	Standard Supreme Sterilization Wrappers
Class:	Class II
Common/Usual Name:	Non-sterile Sterilization Wrappers
Classification Name:	Sterilization Wrap
	Regulation 21 CFR 880.6850, Product Code FRG

Device Description

Standard Supreme Sterilization Wrappers are made from Standard Supreme fabric. This fabric uses intimately blended cotton and polyester yarns, is woven into fabric and then dyed. The fabric comes in three colors – misty, ceil and jade. The dyes used to achieve the three shades include Teresil Navy, Novasol Blue, VatGreen1, Vat Yellow1, and Vat Red31.

Standard Supreme Wrapper Product Line Table

Item	Description	Size (inch)
21520502	Standard Supreme Wrapper, Misty	12x12
21521502	Standard Supreme Wrapper, Misty	18x18
21522002	Standard Supreme Wrapper, Misty	23x23
21522802	Standard Supreme Wrapper, Misty	30x30
21523002	Standard Supreme Wrapper, Misty	35x35
21525002	Standard Supreme Wrapper, Misty	45x45
21526002	Standard Supreme Wrapper, Misty	54x54
21528202	Standard Supreme Wrapper, Misty	54x72
21528802	Standard Supreme Wrapper, Misty	70x70
21531502	Standard Supreme Wrapper, Jade	18x18
21532002	Standard Supreme Wrapper, Jade	23x23
21532302	Standard Supreme Wrapper, Jade	27x27
21532802	Standard Supreme Wrapper, Jade	30x30
21533002	Standard Supreme Wrapper, Jade	35x35
21535002	Standard Supreme Wrapper, Jade	45x45
21536002	Standard Supreme Wrapper, Jade	54x54
21538202	Standard Supreme Wrapper, Jade	54x72
21538802	Standard Supreme Wrapper, Jade	70x70
21541502	Standard Supreme Wrapper, Ceil	18x18
21542002	Standard Supreme Wrapper, Ceil	23x23
21542802	Standard Supreme Wrapper, Ceil	30x30
21543002	Standard Supreme Wrapper, Ceil	35x35
21545002	Standard Supreme Wrapper, Ceil	45x45
21546002	Standard Supreme Wrapper, Ceil	54x54
21548202	Standard Supreme Wrapper, Ceil	54x72
21548802	Standard Supreme Wrapper, Ceil	70x70

Intended Use/Indications for Use

Standard Supreme Sterilization Wrappers are intended to be used to enclose another medical device that is to be sterilized by a health care provider. They are intended to allow sterilization of the enclosed medical device and also to maintain sterility of the enclosed device until used. Standard Supreme Sterilization Wrappers will function as a sterilization wrap when processed according to instructions. Standard Supreme Sterilization Wrappers are reusable through 75 wash, dry, and sterilization cycles. They are manufactured and distributed as non-sterile sterilization wraps that are intended to be sterilized and processed by health care facilities and/or contract sterilization/laundry companies.

Pack Assembly:

Pack assembly should follow established folding, assembly and wrapping procedures as defined by the clinical staff for aseptic presentation of the pack and its contents. The oblong and envelope folds have been validated for use on textile packs. Closure can include autoclave tape and elastomer closures.

Sterilization:

A prevacuum steam sterilization cycle (4 minute exposure at 270^{o}F) has been validated for use on textile packs. The maximum pack size validated for use was 0.58 cubic feet with a pack weight of 12.9 pounds – pack density of 22.4 lbs./cu.ft. The maximum chamber loading configuration included 85.6 pounds of packs in a 9.1 cubic foot chamber – load density of 10.4 lbs./cu.ft.

Performance

Standard Supreme Sterilization Wrappers have successfully completed the non-clinical performance tests listed below.

a. Whole Package Challenge and 30 Day Shelf Life Study – Standard Supreme Sterilization Wrappers demonstrated their ability in these tests to be an effective sterile barrier after 75 cycles of soiling, washing, drying and sterilization when used as a sequential double wrap for textile packs.

b. Strength through 75 wash, dry and sterilization cycles - ASTM #D-5034-2013 >50 psi

c. Linting < 5.0 log IPM. Resists the rigors of linting associated with flexing and abrasion.

d. Cytotoxicity MEM Elution (MG023) – Non-Toxic

e. Sterilization – Sterilization efficiency/penetration for the Standard Supreme Sterilization Wrappers was demonstrated with a half-cycle exposure condition showing no growth of the indicator organism in worst case challenge load configurations. A pre-vacuum steam sterilization cycle (4 minute exposure at 270^{o}F) has been validated for use on textile packs. The maximum pack size validated for use was 0.58 cubic feet with a pack weight of 12.9 pounds – pack density of 22.4 lbs./cu.ft. The maximum chamber loading configuration included 85.6 pounds of packs in a 9.1 cubic foot chamber – load density of 10.4 lbs./cu.ft.

f. Use Life - 75 processing (wash, dry and sterilization).

g. Colorfastness to Commercial Laundering - AATCC #61-1993(4A) >3.5.

Substantial Equivalence Comparison

Standard Supreme Sterilization Wrappers have been shown to be substantially equivalent to WrapPel "T" sterilization wraps K923408. All fabrics used are woven, dyed and treated with a fluoropolymer finish. Fabrics are spread, cut and sewn into the similar if not the exact wrapper size. All products can use color coded thread around the edges to provide easy size identification. Performance through 75 processing demonstrated that Standard Supreme Sterilization Wrappers and WrapPel "T" Sterilization Wrappers have the strength for reuse. Both subject and predicate wrappers can be steam sterilized.

In practice Standard Supreme Sterilization Wrappers differ from WrapPel "T" Sterilization Wrappers in that it is a 55/45 blended cotton/polyester fabric versus WrapPel "T" Sterilization Wrappers which are 100% polyester.

Substantial Equivalence Table
Standard Supreme Sterilization Wrappers (K172207)
vs.
WrapPel "T" Sterilization Wrappers (K923408)

	Standard Supreme Sterilization Wrappers	**WrapPel "T" Sterilization Wrappers**
Manufacturing		
Quality System	21 CFR 820	21 CFR 820
Fabric	Woven (1:1)	Woven (1:1)
Finishing	Vat Dyed	Disperse Dyed & Flurocarbon Treated
Cut-n-Sew	Yes	Yes
Finished Dimensions	Similar/Same	Similar/Same
Performance – Non-clinical tests were used to evaluate the physical and performance characteristics of Standard Supreme Sterilization Wrappers. Performance through 75 processing demonstrated that Standard Supreme Sterilization Wrappers and WrapPel "T" Sterilization Wrappers have the strength for reuse. Both wrappers can be steam sterilized, are colorfast, low lint and non-toxic.		
Strength	>20 psi	>20 psi
Colorfastness	Yes	Yes
Linting	Completed	Completed
Toxicity	Non-Toxic	Non-Toxic
Use Life	75 wash, dry, & sterilizations	75 wash, dry, & sterilizations
Sterilization – Pre-vacuum Steam Cycles		
Cycle – 4 minute exposure at 270°F.	Yes	Yes
Intended Use, i.e., traditional wrapping practices using oblong and envelope folds		
Fabric Packs	Yes	Yes

Substantial Equivalence Conclusion Statement

Based on intended use, bench testing and technological characteristics, Standard Supreme Sterilization Wrappers are substantially equivalent to the predicate device. The non-clinical tests demonstrate that Standard Supreme Sterilization Wrappers are substantially equivalent to the predicate device.