DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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November 4, 2016

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

Re: K162162
Trade/Device Name: Barrier Supreme Sterilization Wrapper
Regulation Number: 21 CFR 880.6850
Regulation Name: Sterilization Wrap
Regulatory Class: Class II
Product Code: FRG
Dated: September 27, 2016
Received: September 27, 2016

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 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,

Michael J. Ryan -S

for Tina Kiang, Ph.D.
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)*

K162162

Device Name

Barrier Supreme Sterilization Wrappers (for models, colors, and sizes, see Table 1 below)

Indications for Use *(Describe)*

Barrier 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.

Barrier Supreme Sterilization Wrappers will function as a sterilization wrap when processed according to instructions. Barrier 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 23.2 pounds – pack density of 40.0 lbs./cu.ft. The maximum chamber loading configuration included 96 pounds of packs in a 9.1 cubic foot chamber – load density of 10.6 lbs./cu.ft.

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

Sizes	Misty	Jade	Ceil
12"x12"	---	--	--
18"x18"	21621502	21631502	21651502
23"x23"	21622002	21632002	21652002
30"x30"	21622802	21632802	21652802
35"x35"	21623002	21633002	21653002
45"x45"	21625002	21635002	21655002
54"x54"	21626002	21636002	21656002
54"x72"	21628202	21638202	21658202
60"x60"	21628502	--	--

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
BARRIER SUPREME STERILIZATION WRAPPERS

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 10/27/2016

Device Information

Device Name:	Barrier 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

Barrier Supreme Sterilization Wrappers are made from Barrier Supreme fabric. This fabric uses intimately blended cotton and polyester yarns, is woven into fabric, dyed and treated with a fluoropolymer finish. 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.

Barrier Supreme Wrapper Product Line Table	
Item	**Description**
21621502	Barrier Supreme Wrapper, Misty 18x18
21622002	Barrier Supreme Wrapper, Misty 23X23
21622802	Barrier Supreme Wrapper, Misty 30x30
21623002	Barrier Supreme Wrapper, Misty 35x35
21625002	Barrier Supreme Wrapper, Misty 45x45
21626002	Barrier Supreme Wrapper, Misty 54x54
21628202	Barrier Supreme Wrapper, Misty 54x72
21628502	Barrier Supreme Wrapper, Misty 60x60
21631502	Barrier Supreme Wrapper, Jade 18x18
21632002	Barrier Supreme Wrapper, Jade 23x23
21632802	Barrier Supreme Wrapper, Jade 30x30
21633002	Barrier Supreme Wrapper, Jade 35x35
21635002	Barrier Supreme Wrapper, Jade 45x45
21636002	Barrier Supreme Wrapper, Jade 54x54
21638202	Barrier Supreme Wrapper, Jade 57x72
21651502	Barrier Supreme Wrapper, Ceil Blue 18x18
21652002	Barrier Supreme Wrapper, Ceil Blue 23x23
21652802	Barrier Supreme Wrapper, Ceil Blue 30x30
21653002	Barrier Supreme Wrapper, Ceil Blue 35x35
21655002	Barrier Supreme Wrapper, Ceil Blue 45x45
21656002	Barrier Supreme Wrapper, Ceil Blue 54x54
21658202	Barrier Supreme Wrapper, Ceil Blue 54x72

Intended Use/Indications for Use

Barrier 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.

Barrier Supreme Sterilization Wrappers will function as a sterilization wrap when processed according to instructions. Barrier 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 23.2 pounds – pack density of 40.0 lbs./cu.ft. The maximum chamber loading configuration included 96 pounds of packs in a 9.1 cubic foot chamber – load density of 10.6 lbs./cu.ft.

Substantial Equivalence Comparison

Barrier 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 processings demonstrate that Barrier Supreme Sterilization Wrappers and WrapPel “T” Sterilization Wrappers have the strength for reuse. Both subject and predicate wrappers can be steam sterilized.

In practice Barrier 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 Conclusion Statement

Based on intended use, bench testing and technological characteristics, Barrier Supreme Sterilization Wrappers are substantially equivalent to the predicate device.

Performance

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

a. Whole Package Challenge and 30 Day Shelf Life Study – Barrier 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 Barrier Supreme Sterilization Wrap was demonstrated with a half-cycle exposure condition showing no growth of the indicator organism in worst case challenge load configurations. 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 23.2 pounds – pack density of 40.0 lbs./cu.ft. The maximum chamber loading configuration included 96 pounds of packs in a 9.1 cubic foot chamber – load density of 10.6 lbs./cu.ft.

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

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

The non-clinical tests demonstrate that Barrier Supreme Sterilization Wrappers are substantially equivalent to the predicate device.

Substantial Equivalence Table

Barrier Supreme Sterilization Wrappers
vs.
WrapPel "T" Sterilization Wrappers (K923408)

	Barrier 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 Barrier Supreme Sterilization Wrappers. Performance through 75 processings demonstrate that Barrier 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 – Prevacuum 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
Substantially Equivalent Conclusion Statement - Based on intended use, bench testing, and technological characteristics, the subject device is substantially equivalent to the predicate device.		