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

July 27, 2016

Ahlstrom Nonwovens LLC
% Lauren Chrapowitzky
Consultant
AJW Technology Consultants, Inc.
445 Apollo Beach Blvd
Apollo Beach, Florida 33572

Re: K160755
Trade/Device Name: Reliance® Solo Sterilization Wrap, Reliance® Tandem Sterilization Wrap
Regulation Number: 21 CFR 880.6850
Regulation Name: Sterilization Wrap
Regulatory Class: Class II
Product Code: FRG
Dated: June 22, 2016
Received: June 24, 2016

Dear Lauren Chrapowitzky:

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 yours,

Tejashri Purohit-Sheth, M.D.

Tejashri Purohit-Sheth, M.D.
Clinical Deputy Director
DAGRID/ODE/CDRH 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 below.

510(k) Number *(if known)*
K160755

Device Name

Reliance® Solo Sterilization Wrap, Reliance® Tandem Sterilization Wrap

Indications for Use *(Describe)*

Ahlstrom Reliance® Tandem and Solo Sterilization Wraps are intended to be used to enclose another medical device that is to be sterilized by a healthcare provider via the following:

- Pre-vacuum Steam 270°F/132°C for 4 minutes
- Gravity Steam 250°F/121°C for 30 minutes
- 100% Ethylene Oxide (EO) with a concentration of 725-735 mg/L @ 131°F/55°C and 40% - 80% relative humidity for 60 minutes
- Advanced Sterilization Products (ASP) STERRAD® 100S
- Advanced Sterilization Products (ASP) STERRAD® 100NX (Standard, Express and Flex cycles)
- STERIS Amsco® V-PRO 1, STERIS Amsco® V-PRO 1 Plus, STERIS Amsco® V-PRO maX Low Temperature Sterilization Systems (Lumen, Non Lumen and Flexible Cycles)

The wrap is intended to allow sterilization of the enclosed medical device(s) and maintain sterility of the enclosed device(s) until used.

Pre-Vacuum Steam Sterilization:

- Validated for dry time of 20 minutes for Models T100/S100, T200/S200, T300/S300.
- Validated for dry time of 30 minutes for Models T400/S400, T500/S500, T600/S600.
- All models of Reliance® Tandem and Solo validated for pre-vacuum steam sterilization with stainless steel lumens (3 mm in diameter or larger and 400 mm in length or less) as part of the load with a maximum weight of 25lbs dependent on the model.

Gravity Steam Sterilization:

- Validated for dry times of 20 minutes for Models T100/S100, T200/S200, T300/S300.
- Validated for dry times of 30 minutes for Models T400/S400.
- Models T100/S100, T200/S200, T300/S300, T400/S400 of Reliance® Tandem and Solo validated for gravity steam sterilization with stainless steel lumens (3 mm in diameteror larger and 400 mm in length or less) as part of the load with a maximum weight of 25lbs dependent on the model.
- Models T500/S500 and T600/S600 are <u>not validated</u> for use for gravity steam sterilization.

Ethylene Oxide Sterilization:

- Validated for aeration time of 8 hours at 55°C
- All models of Reliance® Tandem and Solo validated for ethylene oxide sterilization with stainless steel lumens (3 mm in diameter or larger and 400 mm in length or less) as part of the load with a maximum weight of 25lbs dependent on the model.

Advanced Sterilization Products (ASP) STERRAD® 100S Sterilization

- All models of Reliance® Tandem and Solo validated with ASP STERRAD® 100S sterilization with stainless steel lumens (2 mm inside diameter or larger and a length of 250mm or less) as part of the load with a maximum weight of 10.7lbs dependent on the model.

Advanced Sterilization Products (ASP) STERRAD® 100NX Sterilization

- All models of Reliance® Tandem and Solo validated with ASP STERRAD® 100NX sterilization cycles detailed in Table 1.

Table 1: Validated Advanced Sterilization Products (ASP) STERRAD® 100NX Cycles

Advanced Sterilization Products (ASP) STERRAD® System and Cycle	Intended Load
100NX Standard Cycle	Reusable metal and non-metal medical devices, including up to 10 lumens of the following dimensions per chamber load: • An inside diameter of 0.7mm or larger and a length of 500mm or shorter of single-channel stainless steel lumens.
100NX Flex Cycle	One or two single-channel flexible endoscopes with or without a silicone mat. Flexible endoscope may contain: • A single channel Teflon/PE/PTFE lumen with an inside diameter of 1 mm or larger and a length of 850mm or shorter. (A maximum of two flexible endoscopes, one per tray per sterilization cycle)
100NX Express Cycle	Non-lumened reusable metal and non-metal medical devices requiring surface sterilization, or sterilization of mated stainless steel and titanium surfaces, and rigid or semi-rigid endoscopes without lumens.

STERIS Amsco® V-PRO 1, STERIS Amsco® V-PRO 1 Plus, STERIS Amsco® V-PRO maX Low Temperature Sterilization Systems

- All models of Reliance® Tandem and Solo Sterilization Wraps have been validated for use with STERIS V-PRO® cycles detailed in Table 2.
- Reliance® Tandem and Solo Sterilization Wraps were validated to be effectively aerated during the pre-programmed STERIS Amsco V-PRO® Sterilization Cycles.

Table 2: Validated STERIS Amsco® V-PRO Cycles

STERIS Amsco® V-PRO Cycle	Intended Load
Lumen Cycle	Reusable metal and non-metal medical devices, including up to 20 stainless steel lumens with dimensions of 3.0mm diameter or larger and a length of 400mm or shorter.
Non Lumen Cycle	Non lumened reusable metal and non-metal medical devices.
Flexible Cycle	Single lumen surgical flexible endoscopes and bronchoscopes in the following load configuration: 1.) One tray containing a flexible endoscope with a light cord (if not integral to endoscope) and mat. The flexible endoscope having an inside diameter of 1 mm or larger and a length of 850 mm or shorter. 2.) An additional tray containing non-lumened medical devices.

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)

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510(k) SUMMARY
(as required by 807.92)

I. SUBMITTER

Ahlstrom Nonwovens LLC
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Contact Person: Gary Jackson
Date Prepared: 25 July 2016

REGULATORY CORRESPONDENT

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II. DEVICE

Name of Device: Reliance® Solo Sterilization Wrap, Reliance® Tandem Sterilization Wrap
Common or Usual Name: Sterilization Wrap
Classification Name: Sterilization Wrap
Device Panel: General Hospital
Regulatory Class: II
Product Code: FRG
Regulation Number: 880.6850

III. PREDICATE DEVICE

The Kimberly Clark Kimguard® and Kimguard® ONE-STEP® sterilization wraps, cleared under K082177 is the primary predicate device utilized in this submission.

The following 510(k) numbers, also referencing the Kimberly Clark Kimguard® and Kimguard® ONE-STEP® sterilization wraps, are utilized as secondary predicate devices for this submission:

- K082554, K091685, K141071, K092167, K112805, K113806, K141612

These predicate devices have not been subject to a design-related recall.
No reference devices were used in this submission.

IV. DEVICE DESCRIPTION

The Reliance® Solo and Reliance® Tandem Sterilization Wraps are square or rectangular nonwoven sheets produced using a three-layer SMS (spunbond-meltblown-spunbond) process. The Reliance® SMS Sterilization Wraps are separated into two distinct product offerings:

Reliance® Tandem: Consists of single sheets of SMS wrap, where two sheets are used together for the sequential wrapping of one or a collection of medical devices that will be sterilized following standard healthcare practices.

Reliance® Solo: Consists of two sheets of SMS wrap, ultrasonically bonded together along two edges for convenient simultaneous wrapping of one or a collection of medical devices that will be sterilized following standard healthcare practices.

The Reliance® Solo and Reliance® Tandem Sterilization Wraps are composed of polypropylene with the addition of blue or green pigment and an anti-static treatment. Reliance® Tandem and Reliance® Solo wraps allow a sterilized package of medical devices to be opened aseptically.

Table 1: Dimensional Specifications of Reliance® Tandem and Reliance® Solo Wrap Models

Dimensions	T100/S100	T200/S200	T300/S300	T400/S400	T500/S500	T600/S600
9 in. x 9 in.	x					
12 in. x 12 in.	x	x				
15 in. x 15 in.	x	x				
18 in. x 18 in.	x	x	x	x	x	
20 in. x 20 in.	x					
24 in. x 24 in.	x	x	x	x	x	
30 in. x 30 in.	x	x	x	x	x	
36 in. x 36 in.	x	x	x	x	x	x
40 in. x 40 in.	x	x	x	x		x
45 in. X 45 in.	x		x	x	x	x
48 in. x 48 in.	x	x	x	x	x	x
54 in. x 54 in.	x	x	x	x	x	x
60 in. x 60 in.					x	
54 in. x 72 in.	x	X	x	x	x	x

54 in. x 90 in.					x	

Wrap Model Recommendations

Table 2 provides the recommended wrapped package content weights by model and sterilization modality for the Reliance® Tandem and Solo products.

Table 2: Wrap Model Recommendations[1]

Sterilization Wrap Models	Intended Load	Maximum Recommended Wrapped Package Content Weights[2]				
		Pre-Vacuum and Gravity* Steam and EO	Advanced Sterilization Products (ASP) Sterrad® 100S	Advanced Sterilization Products (ASP) Sterrad® 100NX	Steris Amsco® V-PRO Lumen and Non Lumen Cycle	Steris Amsco® V-PRO Flex Cycle
T100 and S100	Very Light Weight Package (for example: gauze or towel packs or batteries)	3 lbs*	10.7 lbs	10.7 lbs	10.7 lbs	3 lbs
T200 and S200	Light Weight Package (for example: standard linen packs or telescope with light cord)	6 lbs*	10.7 lbs	10.7 lbs	10.7 lbs	6.5 lbs
T300 and S300	Light to Moderate Weight Package (for example: general use medical instruments)	9 lbs*	10.7 lbs	10.7 lbs	10.7 lbs	9 lbs

T400 and S400	Moderate to Heavy Weight Package (for example: general use medical instruments)	13 lbs*	10.7 lbs	10.7 lbs	10.7 lbs	9 lbs
T500 and S500	Heavy Weight Package (for example: general use medical instruments)	17 lbs	10.7 lbs	10.7 lbs	10.7 lbs	9 lbs
T600 and S600	Very Heavy Weight Package (for example: general use medical instruments)	25 lbs	10.7 lbs	10.7 lbs	10.7 lbs	9 lbs

*Gravity Steam Sterilization is validated for models T100/S100, T200/S200, T300/S300, T400/S400 only. T500/S500 and T600/S600 models are not validated for gravity steam.

[1] Individual results may differ due to factors such as variations in wrapping techniques, handling practices and folding methods. Results may also differ due to the use of irregularly shaped contents that may result in 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. In addition, it is recommended to not exceed the number, weight and size of individual content types that were validated Ahlstrom Nonwovens Sterilization Wraps (i.e. wrapped contents).

V. INDICATIONS FOR USE

Ahlstrom Reliance® Tandem and Solo Sterilization Wraps are intended to be used to enclose another medical device that is to be sterilized by a healthcare provider via the following:

- Pre-vacuum Steam 270°F/132°C for 4 minutes
- Gravity Steam 250°F/121°C for 30 minutes
- 100% Ethylene Oxide (EO) with a concentration of 725-735 mg/L @ 131°F/55°C and 40% - 80% relative humidity for 60 minutes
- Advanced Sterilization Products (ASP) STERRAD® 100S
- Advanced Sterilization Products (ASP) STERRAD® 100NX (Standard, Express and Flex cycles)
- STERIS Amsco® V-PRO 1, STERIS Amsco® V-PRO 1 Plus, STERIS Amsco® V-PRO maX Low Temperature Sterilization Systems (Lumen, Non Lumen and Flexible Cycles)

The wrap is intended to allow sterilization of the enclosed medical device(s) and maintain sterility of the enclosed device(s) until used.

Pre-Vacuum Steam Sterilization:

- Validated for dry time of 20 minutes for Models T100/S100, T200/S200, T300/S300.
- Validated for dry time of 30 minutes for Models T400/S400, T500/S500, T600/S600.

- All models of Reliance® Tandem and Solo validated for pre-vacuum steam sterilization with stainless steel lumens (3 mm in diameter or larger and 400 mm in length or less) as part of the load with a maximum weight of 25lbs dependent on the model.

Gravity Steam Sterilization:

- Validated for dry times of 20 minutes for Models T100/S100, T200/S200, T300/S300.
- Validated for dry times of 30 minutes for Models T400/S400.
- Models T100/S100, T200/S200, T300/S300, T400/S400 of Reliance® Tandem and Solo validated for gravity steam sterilization with stainless steel lumens (3 mm in diameter or larger and 400 mm in length or less) as part of the load with a maximum weight of 25lbs dependent on the model.
- Models T500/S500 and T600/S600 are not validated for use for gravity steam sterilization.

Ethylene Oxide Sterilization:

- Validated for aeration time of 8 hours at 55°C
- All models of Reliance® Tandem and Solo validated for ethylene oxide sterilization with stainless steel lumens (3 mm in diameter or larger and 400 mm in length or less) as part of the load with a maximum weight of 25lbs dependent on the model.

Advanced Sterilization Products (ASP) STERRAD® 100S Sterilization

- All models of Reliance® Tandem and Solo validated with ASP STERRAD® 100S sterilization with stainless steel lumens (2 mm inside diameter or larger and a length of 250mm or less) as part of the load with a maximum weight of 10.7lbs dependent on the model.

Advanced Sterilization Products (ASP) STERRAD® 100NX Sterilization

- All models of Reliance® Tandem and Solo validated with ASP STERRAD® 100NX sterilization cycles detailed in Table 1.

Table 1: Validated Advanced Sterilization Products (ASP) STERRAD® 100NX Cycles

Advanced Sterilization Products (ASP) STERRAD® System and Cycle	**Intended Load**
100NX Standard Cycle	Reusable metal and non-metal medical devices, including up to 10 lumens of the following dimensions per chamber load: • An inside diameter of 0.7mm or larger and a length of 500mm or shorter of single-channel stainless steel lumens.
100NX Flex Cycle	One or two single-channel flexible endoscopes with or without a silicone mat. Flexible endoscope may contain: • A single channel Teflon/PE/PTFE lumen with an inside diameter of 1 mm or larger and a length of 850mm or shorter. (A maximum of two flexible endoscopes, one per tray per sterilization cycle)

100NX Express Cycle	Non-lumened reusable metal and non-metal medical devices requiring surface sterilization, or sterilization of mated stainless steel and titanium surfaces, and rigid or semi-rigid endoscopes without lumens.

STERIS Amsco® V-PRO 1, STERIS Amsco® V-PRO 1 Plus, STERIS Amsco® V-PRO maX Low Temperature Sterilization Systems

- All models of Reliance® Tandem and Solo Sterilization Wraps have been validated for use with STERIS V-PRO® cycles detailed in Table 2.
- Reliance® Tandem and Solo Sterilization Wraps were validated to be effectively aerated during the pre-programmed STERIS Amsco V-PRO® Sterilization Cycles.

Table 2: Validated STERIS Amsco® V-PRO Cycles

STERIS Amsco® V-PRO Cycle	**Intended Load**
Lumen Cycle	Reusable metal and non-metal medical devices, including up to 20 stainless steel lumens with dimensions of 3.0mm diameter or larger and a length of 400mm or shorter.
Non Lumen Cycle	Non lumened reusable metal and non-metal medical devices.
Flexible Cycle	Single lumen surgical flexible endoscopes and bronchoscopes in the following load configuration: 1.) One tray containing a flexible endoscope with a light cord (if not integral to endoscope) and mat. The flexible endoscope having an inside diameter of 1 mm or larger and a length of 850 mm or shorter. 2.) An additional tray containing non-lumened medical devices.

VI. COMPARISON OF TECHNOLIGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

Manufacturer	Ahlstrom Nonwovens, LLC	Kimberly-Clark
Device Name	RELIANCE® Tandem and Solo Sterilization Wrap	Kimguard® and Kimguard® ONE-STEP® Sterilization wraps
Intended use	Reliance® Tandem and Solo Sterilization Wrap is intended to be used to enclose another medical device that is to be sterilized by a health care provider	Kimguard® Sterilization Wrap is intended to be used to enclose another medical device that is to be sterilized by a health care provider
Material Composition	Polypropylene spunbond-meltblown-spunbond (SMS) fabric	Polypropylene spunbond-meltblown-spunbond (SMS) fabric

Configurations/ Dimensions	Various	Various
Sterilant Penetration	Pass per ANSI/AAMI ST79:2010 & A1:2010 and ANSI/AAMI/ISO 14937:2009	Substantially Equivalent
Validated for use in Sterilization System	Pre-vacuum Steam 270°F/132°C for 4 minutes	Substantially Equivalent
	Gravity Steam 250°F/121°C for 30 minutes	Same, Plus KC500/KC600
	100% Ethylene Oxide (EO) with a concentration of 725-735 mg/L @ 131°F/55°C and 40% - 80% relative humidity for 60 minutes	Substantially Equivalent
	(ASP) STERRAD® 100S, and 100NX (STANDARD, EXPRESS and Flex cycles)	Same, Plus STERRAD® 50 STERRAD® 200 STERRAD® NX (Standard and Advanced Cycles) STERRAD® 100NX DUO cycle
	STERIS Amsco® V-PRO 1 & V-PRO 1 Plus (Non-Lumen and Lumen cycles) and V-PRO maX cycle	Substantially Equivalent
Microbial Barrier Properties (Packaging Integrity)	Pass	Pass
Material Compatibility	Pass	Pass
Toxicological Properties (Biocompatibility)	Pass	Pass
Maintenance of Sterility	90 days	30 days (KC100, KC200, KC300, KC400, KC500, KC600) 180 days (KC300, KC400, KC500, and KC600) 365 days (KC300, KC400, KC500, and KC600)
Dry Time	Reliance® Tandem and Solo Models T100/S100, T200/S200, T300/S300: 20 minutes Reliance® Tandem and Solo Models T400/S400, T500/S500, T600/S600: 30 minutes	Kimguard® Models KC100, KC200, KC300: 20 minutes Kimguard® Models KC400, KC500, KC600: 30 minutes Kimguard® ONE-STEP® Models KC100, KC200: 20 minutes Kimguard® ONE-STEP® Models KC300, KC400, KC500, KC600: 30 minutes

VII. PERFORMANCE DATA

Summary of Testing:

The Reliance® Tandem and Reliance® Solo Sterilization wrap performance has been tested in accordance with the applicable requirements recommended in Premarket Notification {510(k)} Submissions for Medical Sterilization Packaging Systems in Health Care Facilities; Draft Guidance for Industry and FDA (March 7, 2002). Testing included: biocompatibility (i.e., cytotoxicity) in compliance with the methods of ISO 10993, sterilant penetration, dry time, and physical integrity. The Sterilization wrap has also been tested for the ability to maintain sterility of pack contents after sterilization for up to 90 days under standard conditions. All results of testing met acceptance criteria.

Standards Utilized

- AAMI / ANSI ST79: 2010 & A1:2010 & A2:2011 & A3:2012 & A4:2013, Comprehensive Guide To Steam Sterilization And Sterility Assurance In Health Care Facilities.
- ASTM D737 - 04(2008): Standard Test Method for Air Permeability of Textile Fabrics
- ASTM D3776 - 96 (2002): Standard Test Methods for Mass Per Unit Area (Weight) of Fabric
- ASTM D5034 - 95(2001): Standard Test Method for Breaking Strength and Elongation of Textile Fabrics (Grab Test)
- ASTM F2101-14, Standard Test Method For Evaluating The Bacterial Filtration Efficiency (Bfe) Of Medical Face Mask Materials, Using A Biological Aerosol Of Staphylococcus Aureus. (General Plastic Surgery/General Hospital)
- BS EN 868-2:2009 Packaging for terminally sterilized medical devices. Sterilization wrap. Requirements and test methods
- ISO 9073-4:1997; Textiles -- Test methods for nonwovens -- Part 4: Determination of tear resistance
- AAMI / ANSI / ISO 10993-5:2009/(R) 2014, Biological Evaluation Of Medical Devices -- Part 5: Tests For In Vitro Cytotoxicity
- AAMI / ANSI / ISO 10993-7:2008(R)2012, Biological Evaluation Of Medical Devices - Part 7: Ethylene Oxide Sterilization Residuals
- ISO 14937 Second Edition 2009-10-15, Sterilization Of Health Care Products - General Requirements For Characterization Of A Sterilizing Agent And The Development, Validation And Routine Control Of A Sterilization Process For Medical Devices

VIII. CONCLUSIONS

In conclusion, the Reliance® Tandem and Solo Sterilization wraps are substantially equivalent to the Kimberly-Clark Kimguard® and Kimguard® ONE-STEP® in terms of general intended use, material composition, and configuration. Based on the results of the sterilization validation, shelf-life and physical performance testing, Ahlstrom Reliance® Tandem and Solo sterilization wraps are as safe and as effective, and perform as well as the predicate device, Kimberly-Clark Kimguard® and Kimguard® ONE-STEP®, for their intended use.