



December 7, 2023

Ahlstrom-Munksjo Nonwovens LLC  
% Ryan Burke  
Quality and Regulatory Consultant  
AJW Technology Consultants, Inc.  
11705 Boyette Road, Suite 503  
Riverview, Florida 33569

Re: K230137

Trade/Device Name: Reliance® Fusion Sterilization Wraps  
Regulation Number: 21 CFR 880.6850  
Regulation Name: Sterilization Wrap  
Regulatory Class: Class II  
Product Code: FRG  
Dated: November 8, 2023  
Received: November 9, 2023

Dear Ryan Burke:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (<https://www.fda.gov/media/99812/download>) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (<https://www.fda.gov/media/99785/download>).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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](mailto:DICE@fda.hhs.gov)) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Colin  
O'Neill -S 

Colin O'Neill, M.B.E.

Assistant Director

DHT6B: Division of Spinal Devices

OHT6: Office of Orthopedic Devices

Office of Product Evaluation and Quality

Center for Devices and Radiological Health

Enclosure

## Indications for Use

510(k) Number (if known)  
K230137

Device Name  
Reliance® Fusion Sterilization Wraps

### Indications for Use (Describe)

Reliance® Fusion 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
  - Dry time of 12 minutes for Fusion Light
  - Dry time of 20 minutes for Fusion Heavy
  - Pre-vacuum steam sterilization of two stainless steel lumens 3 mm in diameter or larger and 400 mm in length or less.
  
- 100% Ethylene Oxide (EO) with a concentration of 725-759 mg/L @ 131°F/55°C and 40% - 70% relative humidity for 60 minutes
  - Aeration time of 8 hours at 55oC
  - Ethylene oxide sterilization of two stainless steel lumens 3 mm in diameter or larger and 400 mm in length or less.

Table 1: Reliance® Fusion Models and Load Recommendations

Wrap Code	Material Type	Intended Load	Wrap Sheet Size, Maximum Recommended Wrapped Package Content Weight: Pre-Vacuum Steam and Ethylene Oxide <sup>1</sup>									
			12" x 12"	15" x 15"	18" x 18"	24" x 24"	30" x 30"	36" x 36"	40" x 40"	48" x 48"	54" x 54"	54" x 72"
Reliance® Fusion Light	Outer SMS / Inner Absorbent Wetlaid Layer	Light to Moderate Weight Package (e.g. general use medical instruments)	1.8 lb	2.0 lb	2.4 lb	3.2 lb	4.3 lb	5.7 lb	6.7 lb	9 lb	9 lb	9 lb
Reliance® Fusion Heavy	Outer SMS / Inner Absorbent Wetlaid Layer	Very Heavy Weight Package (e.g. general use medical instruments)	1.8 lb	2.6 lb	3.7 lb	6.4 lb	9.9 lb	14.2 lb	17.5 lb	25 lb	25 lb	25 lb

<sup>1</sup> 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 for Reliance® Fusion Sterilization Wraps (i.e. wrapped contents).

Table 2: Fusion Wrap Models, sheet color

Reliance® Fusion Models	Wrap Layer	Individual Sheet Color
Light	Outer Layer	Light Blue
	Inner Layer	Green
Heavy	Outer Layer	Dark Blue
	Inner Layer	Green

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.”*

**I. SUBMITTER**

AHLSTROM NONWOVENS LLC  
2 Elm Street  
Windsor Locks, CT 06096  
Phone: (860) 654-8556

Contact Person:  
Gary Jackson Regulatory Affairs  
gary.jackson@ahlstrom.com  
Date Prepared: December 6, 2023

**II. DEVICE**

**Name of Device:** Reliance® Fusion Sterilization Wraps  
**Common or Usual Name:** Sterilization Wrap  
**Classification Name:** Sterilization Wrap (21 CFR 880.6850)  
**Regulatory Class:** 2  
**Product Code:** FRG

**III. PREDICATE DEVICE**

Primary Predicate:  
Reliance® Solo and Reliance® Tandem Sterilization Wrap, K171533

510(k)	Device Name	Regulation Number and Classification Name	Device Class and Product Code
K171533	Reliance® Solo Sterilization Wrap, Reliance® Tandem Sterilization Wrap	21 CFR 880.6850 Wrap, Sterilization	Class 2, FRG

No reference devices were used in this submission.

**IV. DEVICE DESCRIPTION**

The Reliance® Fusion Sterilization Wraps are square or rectangular nonwoven sheets consisting of two layers of nonwoven 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 Fusion wraps consist of two distinct nonwovens for each layer.

**Outer Layer:** SMS nonwoven layer produced using a spunbond-meltblown-spunbond process and composed of polypropylene with blue pigment and an anti-static treatment.

## K230137 510(k) Summary

**Inner Layer:** Wetlaid nonwoven, produced using a wood pulp process, composed of natural wood pulp and synthetic fibers bonded with a synthetic binder, containing green pigment and treated to impart hydrophilic properties.

The Reliance® Fusion Sterilization Wraps allow a sterilized package of medical devices to be opened aseptically and are supplied in a variety of sheet sizes ranging from 12 in. x 12 in. to 54in x 72 in. The Sterilization Wraps have no intended patient contact and are supplied non-sterile. They are for Single Use Only.

### V. INDICATIONS FOR USE

Reliance® Fusion 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
  - Dry time of 12 minutes for Fusion Light
  - Dry time of 20 minutes for Fusion Heavy
  - Pre-vacuum steam sterilization of two stainless steel lumens 3 mm in diameter or larger and 400 mm in length or less.
- 100% Ethylene Oxide (EO) with a concentration of 725-759 mg/L @ 131°F/55°C and 40% - 70% relative humidity for 60 minutes
  - Aeration time of 8 hours at 55°C
  - Ethylene oxide sterilization of two stainless steel lumens 3 mm in diameter or larger and 400 mm in length or less.

Table 1: Reliance® Fusion Models and Load Recommendations

			Wrap Sheet Size, Maximum Recommended Wrapped Package Content Weight: Pre-Vacuum Steam and Ethylene Oxide <sup>1</sup>									
Wrap Code	Material Type	Intended Load	12" x 12"	15" x 15"	18" x 18"	24" x 24"	30" x 30"	36" x 36"	40" x 40"	48" x 48"	54" x 54"	54" x 72"
Reliance® Fusion Light	Outer SMS / Inner Absorbent Wetlaid Layer	Light to Moderate Weight Package (e.g. general use medical instruments)	1.8 lb	2.0 lb	2.4 lb	3.2 lb	4.3 lb	5.7 lb	6.7 lb	9 lb	9 lb	9 lb
Reliance® Fusion Heavy	Outer SMS / Inner Absorbent Wetlaid Layer	Very Heavy Weight Package (e.g. general use medical instruments)	1.8 lb	2.6 lb	3.7 lb	6.4 lb	9.9 lb	14.2 lb	17.5 lb	25 lb	25 lb	25 lb

<sup>1</sup>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 for Reliance® Fusion Sterilization Wraps (i.e. wrapped contents).

## K230137 510(k) Summary

Table 2: Fusion Wrap Models, sheet color

Reliance® Fusion Models	Wrap Layer	Individual Sheet Color
Light	Outer Layer	Light Blue
	Inner Layer	Green
Heavy	Outer Layer	Dark Blue
	Inner Layer	Green

### VI. TECHNOLOGICAL CHARACTERISTICS COMPARISON TABLE

Element of Comparison	PREDICATE:  RELIANCE® Solo and Tandem Sterilization Wrap	SUBJECT (Modified Device):  RELIANCE® Fusion Sterilization Wrap	Comparison to Predicate
510(k) Number	K171553	K230137	NA
Regulation Number	21 CFR 880.6850	21 CFR 880.6850	Same
Product Code	FRG	FRG	Same
Device Classification	2	2	Same
Classification Name	Wrap, Sterilization	Wrap, Sterilization	Same
Indications for Use	<p>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:</p> <p>Pre-vacuum Steam 270°F/132°C for 4 minutes: Validated for dry time of 20 minutes for Models T100/S100, T200/S200, T300/S300. x 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 as part of the load with a maximum weight of 25lbs dependent on the model</p> <p>100% Ethylene Oxide (EO) with a concentration of 725-735 mg/L @ 131°F/55°C and 40% - 80% relative humidity for 60 minutes Validated for aeration time of 8</p>	<p>Ahlstrom Reliance® Fusion Sterilization Wraps are intended to be used to enclose another medical device that is to be sterilized by a healthcare provider via the following:</p> <p>Pre-vacuum Steam 270°F/132°C for 4 minutes: -Dry time of 12 minutes for Reliance® Fusion Light -Dry time of 20 minutes for Fusion Heavy -Pre-vacuum steam sterilization using two stainless steel lumens 3 mm in diameter or larger and 400 mm in length or less.</p> <p>100% Ethylene Oxide (EO) with a concentration of 725-759 mg/L @ 131°F/55°C and 40% - 70% relative humidity for 60 minutes:</p>	Similar See note 1A

K230137 510(k) Summary

	<p>hours at 55°C. All models of Reliance® Tandem and Solo validated for ethylene oxide sterilization with stainless steel lumens as part of the load with a maximum weight of 25lbs dependent on the model.</p> <p>The wrap is intended to allow sterilization of the enclosed medical device(s) and maintain sterility of the enclosed device(s) until used.</p>	<p>-Aeration time of 8 hours at 55°C -Two stainless steel lumens 3 mm in diameter or larger and 400 mm in length or less.</p> <p>The wrap is intended to allow sterilization of the enclosed medical device(s) and maintain sterility of the enclosed device(s) until used.</p> <p><b>See also the Indications for Use statement in Section V for Tables 1 &amp; 2.</b></p>	
<p><b>Indications for Use</b></p>	<p>-Gravity Steam 250°F/121°C for 30 minutes</p> <p>-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)</p> <p><b>Advanced Sterilization Products (ASP) STERRAD® 100S</b> <b>Sterilization:</b> All models of Reliance® Tandem and Solo validated with ASP STERRAD® 100S sterilization with stainless steel lumens as part of the load with a maximum weight of 10.7lbs dependent on the model.</p> <p><b>Advanced Sterilization Products (ASP) STERRAD® 100NX</b> <b>Sterilization:</b> All models of Reliance® Tandem and Solo validated with ASP STERRAD® 100NX sterilization cycles</p>	<p>Not to be Used</p>	<p>Different See note 5A</p>

K230137 510(k) Summary

	<p><b>Validated Advanced Sterilization Products (ASP) STERRAD® 100NX Cycles Advanced Sterilization Products (ASP) STERRAD® System and Cycle:</b></p> <p>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.</p> <p>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)</p> <p>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.</p> <p><b>STERIS Amsco® V-PRO 1, STERIS Amsco® V-PRO 1 Plus, STERIS Amsco® V-PRO maX Low Temperature Sterilization Systems:</b> All models of Reliance® Tandem and Solo Sterilization Wraps have been validated for use with STERIS VPRO® cycles. Reliance® Tandem and Solo Sterilization Wraps were validated to be effectively aerated during the preprogrammed STERIS Amsco V-PRO® Sterilization Cycles.</p> <p><b>Validated STERIS Amsco® V-PRO Cycles STERIS Amsco® V-PRO Cycle:</b></p> <p>Lumen Cycle: Reusable metal and non-metal medical devices, including up to 20 stainless steel lumens with</p>		
--	---	--	--

## K230137 510(k) Summary

	<p>dimensions of 3.0mm diameter or larger and a length of 400mm or shorter.</p> <p>Non Lumen Cycle: Non lumened reusable metal and non-metal medical devices.</p> <p>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.</p>		
<b>Manufacturer</b>	Ahlstrom Nonwovens LLC	Ahlstrom Nonwovens LLC	Same
<b>Intended Use</b>	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	Reliance® Fusion Sterilization Wrap is intended to be used to enclose another medical device that is to be sterilized by a health care provider	Similar
<b>Product Name</b>	Reliance® Solo S100, Reliance® Solo S200, Reliance® Solo S300, Reliance® Solo S400, Reliance® Solo S500, Reliance® Solo, S600	Reliance® Fusion Light, Reliance® Fusion Heavy	Different. No product impact.
<b>Material Composition</b>	<p><b>OUTER LAYER:</b> Polypropylene spunbond-meltblown-spunbond (SMS) nonwoven fabric</p> <p><b>INNER LAYER:</b> Polypropylene spunbond-meltblown-spunbond (SMS) nonwoven fabric</p>	<p><b>OUTER LAYER:</b> Polypropylene spunbond-meltblown-spunbond (SMS) nonwoven fabric</p> <p><b>INNER LAYER:</b> Absorbent Wetlaid nonwoven fabric</p>	Different. See note 2A.
<b>Drying Time</b>	<p>Reliance® Tandem and Solo Models T100/S100, T200/S200, T300/S300: <u>20 minutes</u></p> <p>Reliance® Tandem and Solo Models T400/S400, T500/S500, T600/S600: <u>30 minutes</u></p>	<p>Reliance® Fusion Light: <u>12 minutes</u></p> <p>Reliance® Fusion Heavy: <u>20 minutes</u></p>	Different. See note 3A
<b>Configurations / Dimensions</b>	<p>Sheet sizes: 12 inch x 12 inch, 15 inch x 15 inch, 18 inch x 18 inch, 24 inch x 24 inch, 30 inch x 30 inch, 36 inch x 36 inch, 40 inch x 40 inch,</p>	<p>Sheet sizes: 12 inch x 12 inch, 15 inch x 15 inch, 18 inch x 18 inch, 24 inch x 24 inch, 30 inch x 30 inch, 36 inch x 36 inch, 40 inch x 40 inch,</p>	Same

## K230137 510(k) Summary

	48 inch x 48 inch, 54 inch x 54 inch, 54 inch x 72 inch	48 inch x 48 inch, 54 inch x 54 inch, 54 inch x 72 inch	
<b>Sterilant Penetration</b>	Pass per ANSI/AAMI ST79:2010 & A1:2010 and ANSI/AAMI/ISO 14937:2009	Pass per ANSI/AAMI ST79:2017, ANSI/AAMI/ISO 14937:2009/(R)2013	Similar. See note 4A
<b>Maintenance of Sterility</b>	180 days	180 days	Similar
<b>Sterilization Parameters</b>	100% Ethylene Oxide (EO) with a concentration of 725-735 mg/L @ 131°F/55°C and 40% - 80% relative humidity for 60 minutes	100% Ethylene Oxide (EO) with a concentration of 725-759 mg/L @ 131°F/55°C and 40% - 70% relative humidity for 60 minutes	Similar
	Pre-vacuum Steam 270°F/132°C for 4 minutes	Pre-vacuum Steam 270°F/132°C for 4 minutes	Same
	Gravity Steam 250°F/121°C for 30 minutes	N/A – Not for use with Gravity Steam	Different. See note 5A
	(ASP) STERRAD® 100S, and 100NX (STANDARD, EXPRESS and FLEX cycles)	N/A – Not for use with STERRAD Sterilizers	Different. See note 5A
	STERIS Amsco® V-PRO 1 & V-pro 1 Plus (Non-Lumen and Lumen Cycles) and V-PRO maX cycle	N/A – Not for use with V-PRO Sterilizers	Different. See note 5A
<b>Microbial Barrier Properties (Packaging Integrity)</b>	Microbial Aerosol Challenge Test, Pre-Vacuum Steam and Ethylene Oxide Gauze fallout samples ≥400 CFU/cm <sup>2</sup> Pass	Microbial Aerosol Challenge Test, Pre-Vacuum Steam and Ethylene Oxide Gauze fallout samples ≥400 CFU/cm <sup>2</sup> Pass	Same
<b>Material Compatibility</b>	Pass	Pass	Same
<b>Toxicological Properties (Biocompatibility)</b>	Pass	Pass	Same
<b>Pigment Contents</b>	Pigment Blue, Pigment Violet, Pigment Red, Pigment White, Pigment Black, Pigment Green	Pigment Blue, Pigment Violet, Pigment Red, Pigment White, Pigment Black, Pigment Green, Pigment Yellow	Different. See note 6A
<b>Composition of Materials</b>	Polypropylene	Polypropylene, Cellulose, Polyester, & Acrylic binder	Different. See Note 7A
<b>Shelf Life (Nonsterile)</b>	5 years	3 years	Different. See Note 8A

**Note 1A:** Differences for Pre-vacuum Steam: Testing of modified device confirms safety and efficacy for intended use at modified dry time. For Ethylene Oxide, concentration and humidity were similar due to worst case validation sterilization parameters for the modified device studies. For predicate peroxide sterilization: different, due to peroxide sterilization being incompatible with the inner wetlaid layer.

**Note 2A:** No impact on safety or efficacy for intended use based on biocompatibility and simulated use testing.

**Note 3A:** Dry Time validations and simulated use testing confirm safety and efficacy for intended use.

## K230137 510(k) Summary

**Note 4A:** Changes in standard revision did not impact test methodology used.

**Note 5A:** Differences are outside the scope of the proposed devices intended use and will not affect the safety and efficacy for its intended use.

**Note 6A:** No impact on safety or efficacy for intended use based on biocompatibility and simulated use testing.

**Note 7A:** No impact on safety or efficacy for intended use based on results of biocompatibility and validation testing.

**Note 8A:** No impact on safety or efficacy for intended use within the shelf-life period based on performance testing.

### VII. PERFORMANCE DATA

Performance data for the Reliance Fusion Sterilization Wraps confirm that the device conforms to design specifications. Clinical data was not required for this submission.

#### Summary of Non-Clinical Testing

Test Performed	Standards	Acceptance Criteria	Predicate Device	Proposed Device	Comments
Sterilization Penetration / Efficacy	<p>Sterilization Efficacy Validation, half-cycle, Pre-Vacuum Steam and Ethylene Oxide</p> <p>ANSI/AAMI ST79:2010 &amp; A1:2010 (Predicate)</p> <p>ANSI/AAMI ST79:2017 (Proposed Device)</p> <p>ANSI/AAMI/ISO 14937:2009/(R)2013</p>	All Test Samples and BIs negative for growth following minimum incubation period; Integrators/indicators demonstrate sterility penetration	Pass	Pass	Similar
Dry Time Validation Study	<p>Dry Time Validation Study, Pre-Vacuum Steam (4 min. @ 132C)</p> <p>ANSI/AAMI ST79:2010 &amp; A1:2010 (Predicate)</p> <p>ANSI/AAMI ST79:2017 (Proposed Device)</p>	Average pre- and post-sterilization weight difference of less than 0.2% within 5 min of cycle completion; Tray, contents and sterilization wrap free of visible moisture following cooling period	Pass	Pass	Similar
Maintenance of Package Sterility	<p>180 Day Event Related Shelf Life Study, Pre-Vacuum Steam and Ethylene Oxide</p> <p>ANSI/AAMI ST79:2010 &amp; A1:2010 (Predicate)</p> <p>ANSI/AAMI ST79:2017 (Proposed Device)</p> <p>ANSI/AAMI/ISO 14937:2009/(R)2013</p>	Negative for growth	Pass	Pass	Same

## K230137 510(k) Summary

Test Performed	Standards	Acceptance Criteria	Predicate Device	Proposed Device	Comments
Microbial Barrier	Microbial Aerosol Challenge Test, Pre-Vacuum Steam and Ethylene Oxide	Gauze fallout samples $\geq 400$ CFU/cm <sup>2</sup>	Pass	Pass	Same
Biocompatibility	ISO 10993-5:2009 Tests for in vitro cytotoxicity	Less than or equal to mild cellular reactivity	Pass	Pass	Same
Ethylene Oxide (EO) and Ethylene Chlorohydrin (ECH) Residual Analysis	ISO 10993-7:2008/(R)2012	EO residuals $\leq 4$ mg of EO/ADD ECH residuals $\leq 9$ mg of ECH/ADD All EO Tolerable Contact Limits (TCL) $\leq 10\mu\text{g}/\text{cm}^2$ of EO/ADD All ECH Tolerable Contact Limits (TCL) $\leq 5$ mg/cm <sup>2</sup> of ECH/ADD	Pass	Pass	Same
Material Compatibility: Physical Property Testing Non-Sterile & Sterile	Air Permeability ASTM D737-04	Meets physical property specifications, Non-Sterile and after Pre-vacuum Steam or Ethylene Oxide Sterilization Processes	Pass	Pass	Different, See note 1B
	Basis Weight ASTM D3776-96		Pass	Pass	
	Bursting Strength WSP 30.1.R3 (12)		Pass	Pass	
	Grab Tensile CD ASTM D5034-95		Pass	Pass	
	Trapezoid Tear MD ISO 9073-4		Pass	Pass	
	Hydrohead WSP.080.6.R4 (12)		Pass	Pass	
	Bacterial Filtration Efficiency  ASTM F2101-07 / EN14683:2014 (Predicate)  ASTM F2101-19 and ASTM F2101-23 (Subject Device)		Pass	Pass	
	Gelbo Linting ISO 9073-10:2003		Pass	Pass	

**Note 1B:** Differences in test standard revision numbers have no impact on test methodology and therefore no impact on safety or efficacy of the proposed device.

**NON-CLINICAL TEST CONCLUSION**

In summary, pre-, and post-sterilization physical performance test results of Reliance® Fusion wrap models demonstrate the robustness required of sterilization wraps. The non-clinical tests were selected to evaluate the overall performance criteria needed to ensure safety and efficacy of the proposed device.

**VIII. CONCLUSIONS**

The conclusions drawn from the non-clinical tests demonstrate that the proposed device is as safe, as effective, and performs as well as or better than the predicate device K171533.