Kenpax International Limited
℅ Ray Wang
General Manager
Beijing Believe-Med Technology Service Co.,Ltd
Rm.912, Building #15, XiYueHui, No.5, YiHe North Rd.
FangShan District, BeiJing, 102401
China

March 23, 2023

Re: K222151
Trade/Device Name: Sterilization Wrap
Regulation Number: 21 CFR 880.6850
Regulation Name: Sterilization Wrap
Regulatory Class: Class II
Product Code: FRG
Dated: February 17, 2023
Received: February 21, 2023

Dear Ray Wang:

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,

Eileen Cadel -S
Digitally signed by Eileen Cadel -S
Date: 2023.03.23 12:49:17 -04'00'

for

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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K222151

Device Name
Sterilization Wrap

Indications for Use *(Describe)*
The wrap is intended to allow sterilization of the enclosed medical device(s) and to maintain sterility of the enclosed device(s) until used up to 365 days post sterilization.
Sterilization Wrap is intended to be used to enclose another medical device that is to be sterilized by a health care provider using:
a) 100% ethylene oxide (EO) with a concentration of 725 - 735 mg/l at 131°F/55°C and 40%-80% relative humidity for 60 minutes.
b) Exhausting the EO gas vacuum depth: 157 mBar to 160 mBar
c) Aeration time：12 hours
d) Aeration temperature: 55°C
e) Aeration pressure : 841 mBar to 864 mBar
Suggestions for the packaging content are given in table , A single layer of wrapping needs to be packaged in two sheets.
Table : Wrap Model Recommendations

Series (product family)	Product Code	Size: Length x Width (Inch)	Layers of sheet	Color	Basic Weight (g/m2)	Enclosed Medical Device	Maximum Recommended Wrapped Package Content Weights (lb)
BW1000	BW1015	15*15	Dual	White + Blue	34g + 34g	Very light weight package (For example: Huck towels)	0.78
	BW1024	24*24	Dual	White + Blue			2.96
BL1000	BL1012	12*12	Single	Blue	34g	Very light weight package (For example: Huck towels)	0.37
	BL1015	15*15	Single	Blue			0.78
	BL1018	18*18	Single	Blue			1.11
	BL1020	20*20	Single	Blue			2.32
	BL1024	24*24	Single	Blue			2.98
BW3000	BW3024	24*24	Dual	White + Blue	65g + 65g	Light to moderate weight package (for example: Huck towels, Fluid-resistant table cover, General use medical instruments)	7.5
	BW3036	36*36	Dual	White + Blue			9

BL4000	BL4018	18*18	Single	Blue	70g	Moderate to heavy weight package (for example: Tray liners, Lumens, General use medical instruments). Maximum two lumens in one pack, each with minimum inner diameter of 3 mm ID and maximum length of 400mm.	3.5
BW5000	BW5024	24*24	Dual	White + Blue	70g + 70g	Heavy weight package (for example: Tray liners, Lumens, General use medical instruments) Maximum two lumens in one pack, each with minimum inner diameter of 3 mm ID and maximum length of 400mm.	6
	BW5036	36*36	Dual	White + Blue			9.5
	BW5048	48*48	Dual	White + Blue			17
BW6000	BW6036	36*36	Dual	White + Blue	88g + 88g	Very heavy weight package (for example: Tray liners, Lumens, General use medical instruments). Maximum two lumens in one pack, each with minimum inner diameter of 3 mm ID and maximum length of 400mm.	10
	BW6045	45*45	Dual	White + Blue			23
	BW6048	48*48	Dual	White + Blue			25

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.

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The assigned 510(k) Number: K222151

510(k) Summary

This 510(k) Summary of 510(k) safety and effectiveness information is being submitted in accordance with requirements of SMDA 1990 and Title 21, CFR Section 807.92.

1. Date of Preparation: 23/03/2023

2. Sponsor Identification

KENPAX INTERNATIONAL LIMITED

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3. Designated Submission Correspondent

Mr. Ray Wang

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4. Identification of Proposed Device

Trade Name: Sterilization Wrap
Common Name: Sterilization Wrap

Regulatory Information
Classification Name: Sterilization Wrap
Classification: 2
Product Code: FRG
Regulation Number: 21 CFR 880.6850
Review Panel: General Hospital

Indication For Use Statement:

The wrap is intended to allow sterilization of the enclosed medical device(s) and to maintain sterility of the enclosed device(s) until used up to 365 days post sterilization.
Sterilization Wrap is intended to be used to enclose another medical device that is to be sterilized by a health care provider using:
a) 100% ethylene oxide (EO) with a concentration of 725 - 735 mg/l at 131 °F/55°C and 40%-80% relative humidity for 60 minutes.
b) Exhausting the EO gas vacuum depth: 157 mBar to 160 mBar
c) Aeration time: 12 hours
d) Aeration temperature: 55°C
e) Aeration pressure: 841 mBar to 864 mBar
Suggestions for the packaging content are given in table 1, A single layer of wrapping needs to be packaged in two sheets.

Table 1: Wrap Model Recommendations

Series (product family)	**Product Code**	**Size: Length x Width (Inch)**	**Layers of sheet**	**Color**	**Basic Weight (g/m2)**	**Enclosed Medical Device**	**Maximum Recommended Wrapped Package Content Weights (lb)**
BW1000	BW1015	15*15	Dual	White + Blue	34g + 34g	Very light weight package (For example: Huck towels)	0.78
	BW1024	24*24	Dual	White + Blue			2.96
BL1000	BL1012	12*12	Single	Blue	34g	Very light weight package (For example: Huck towels)	0.37
	BL1015	15*15	Single	Blue			0.78
	BL1018	18*18	Single	Blue			1.11
	BL1020	20*20	Single	Blue			2.32
	BL1024	24*24	Single	Blue			2.98
BW3000	BW3024	24*24	Dual	White + Blue	65g + 65g	Light to moderate weight package (for example: Huck towels, Fluid-resistant table cover, General use medical instruments)	7.5
	BW3036	36*36	Dual	White + Blue			9
BL4000	BL4018	18*18	Single	Blue	70g	Moderate to heavy weight package (for example: Tray liners, Lumens, General use medical instruments). Maximum two lumens in one pack, each with minimum inner diameter of 3 mm ID and maximum length of 400mm.	3.5

BW5000	BW5024	24*24	Dual	White + Blue	70g + 70g	Heavy weight package (for example: Tray liners, Lumens, General use medical instruments) Maximum two lumens in one pack, each with minimum inner diameter of 3 mm ID and maximum length of 400mm.	6
	BW5036	36*36	Dual	White + Blue			9.5
	BW5048	48*48	Dual	White + Blue			17
BW6000	BW6036	36*36	Dual	White + Blue	88g + 88g	Very heavy weight package (for example: Tray liners, Lumens, General use medical instruments). Maximum two lumens in one pack, each with minimum inner diameter of 3 mm ID and maximum length of 400mm.	10
	BW6045	45*45	Dual	White + Blue			23
	BW6048	48*48	Dual	White + Blue			25

5. Device Description

Sterilization Wrap is single use, non-sterile provide. It is divided into single and double layers, with double layer edges closed by ultrasonic suture. The sterilization Wrap is made from 100% polypropylene spunbond- meltblown - spunbond (SMS), not made with natural rubber latex.

The Model/Specifications as below:

Table 2: Model/Specifications of the sterilization wrap

Model / Specifications (in)	BW1000	BW3000	BW5000	BW6000	BL1000	BL4000
12*12					BL1012	
15*15	BW1015				BL1015	
18*18					BL1018	BL4018
20*20					BL1020	
24*24	BW1024	BW3024	BW5024		BL1024	
36*36		BW3036	BW5036	BW6036		
45*45				BW6045		
48*48			BW5048	BW6048		
Basic weight (g/m^2)	34g+34g	65g + 65g	70g + 70g	88g + 88g	34g	70g
Color	Blue + White				Blue	
Layer	Dual layers				Single layer	

Note:

a) BW series is double layer, Double Layer wrap comprised of one sheet of blue pigmented SMS fabric and one sheet of white pigmented SMS fabric that have been ultrasonically sealed on two opposing edges, BL series is single layer, Single Layer wrap comprised of a single sheet of blue pigmented SMS fabric.

b) The specific model under the product series is expressed as series number and size, such as: 24*24inch under the BW1000 series, the model is expressed as: BW1024.

6. Identification of Predicate Device(s)

Primary Predicate Device
510(k) Number: K181174
Product Name: Cardinal Health ™ Sterilization Wrap
Manufacturer: Cardinal Health 200 LLC
Classification: 2
Product Code: FRG
Regulation Number: 21 CFR 880.6850

7. Technological Characteristics

Table 1 General Comparison

ITEM	Proposed Device	Predicate Device (K181174)	Remark
Intended Use	The wrap is intended to allow sterilization of the enclosed medical device(s) and to maintain sterility of the enclosed device(s) until used up to 365 days post sterilization. Sterilization wrap is intended to be used to enclose another medical device that is to be sterilized by a health care provider using: a) 100% ethylene oxide (EO) with a concentration of 725 - 735 mg/l at 131°F/55°C and 40%-80% relative humidity for 60 minutes. b) Exhausting the EO gas vacuum depth: 157 mBar to 160 mBar c) Aeration time：12 hours d) Aeration temperature: 55°C e) Aeration pressure: 841 mBar to 864 mBar	**Cardinal Health™ Sterilization Wrap is intended to enclose another medical device that is to be sterilized by a health care provider using:** • Pre-vacuum steam at 270°F/132°C for 4 minutes • Gravity steam at 250°F/121°C for 30 minutes **• 100% ethylene oxide (EO) with a concentration of 725-735 mg/L at 131°F/55°C and 40%-80% relative humidity for 60 minutes** • Advanced Sterilization Products (ASP) STERRAD® 100S System • Advanced Sterilization Products (ASP) STERRAD® 200 System • Advanced Sterilization Products (ASP) STERRAD® NX System, Standard and Advanced Cycles • Advanced Sterilization Products (ASP) STERRAD® 100NX, Standard, Flex, Express, and DUO cycles • Lumen, Non Lumen, and Flexible Cycles by the STERIS V-PRO® 1, V-PRO® 1 Plus, V-PRO® maX and V-PRO® 60 Low Temperature Sterilization Systems • TSO3 STERIZONE® VP4 System Cycle 1 **The wrap is intended to allow sterilization of the enclosed medical device(s) and to maintain sterility of the enclosed device(s) until used.**	Analyze 1
Product Code	FRG	FRG	SAME
Regulation Number	880.6850	880.6850	SAME
Prescription vs. OTC	OTC	OTC	SAME
Single Use Only vs. Reusable	Single Use only	Single Use only	SAME

510(k) Summary

Materials	Polypropylene fabric using SMS (spunboundmeltdown-spunbound) production process	Polypropylene fabric using SMS (spunboundmeltdown-spunbound) production process	SAME
Chemical Properties	Polypropylene antistatic treatment	Polypropylene antistatic treatment	SAME
Device Design	Double Layer: Double Layer wrap comprised of one sheet of blue pigmented SMS fabric and one sheet of white pigmented SMS fabric that have been ultrasonically sealed on two opposing edges Single Layer: Single Layer wrap comprised of a single sheet of blue pigmented SMS fabric	Dual layer, fold-over: Double layer wrap comprised of a single sheet of blue pigmented SMS fabric that has been folded over in half and ultrasonically sealed to itself on the three nonfolded edges Dual Layer: Double layer wrap comprised of two separate sheets of blue pigmented SMS fabric that have been ultrasonically sealed on two opposing edges Single Layer: Single layer wrap comprised of a single sheet of blue pigmented SMS fabric Two Color: Double layer wrap comprised of one sheet of blue pigmented SMS fabric and one sheet of green pigmented SMS fabric that have been ultrasonically sealed on two opposing edges	Analyze 2
Color	Dual Layer: Blue + White Single Layer: Blue	Dual Layer: Blue + green Single Layer: Blue	Analyze 3

Sterilization	100% ethylene oxide (EO) with a concentration of 725- 735 mg/L at 131ºF/55ºCand 40%- 80% relative humidity for 60 minutes	Pre-vacuum steam at 270ºF/132ºC for 4 minutes Gravity steam at 250°F/121°C for 30 minutes **100% ethylene oxide (EO) with a concentration of 725- 735 mg/L at 131ºF/55ºCand 40%- 80% relative humidity for 60 minutes** Advanced Sterilization Products (ASP) STERRAD® 100S System Advanced Sterilization Products (ASP) STERRAD® 200 System Advanced Sterilization Products (ASP) STERRAD® NX System, Standard and Advanced Cycles Advanced Sterilization Products (ASP) STERRAD® 100NX, Standard, Flex, Express, and DUO cycles Lumen, Non-Lumen, and Flexible Cycles in the STERIS V-PRO® 1, V-PRO® 1 Plus, VPRO® maX and VPRO® 60 Low Temperature Sterilization Systems TSO3 STERIZONE® VP4 System Cycle 1	Analyze 4
Maximum Wrapped	EO: up to 25 pounds	Pre-vacuum Steam: 3 to 25 pounds	SAME

Package Content Weights		Gravity Steam: 3 to 25 pounds **EO: 3 to 25 pounds** STERRAD® 100S: 3 to 9.7 pounds STERRAD® 200: 9.12 pounds STERRAD® NX: 10.7 pounds STERRAD® 100NX: 10.7 pounds STERIS V-PRO® 1, VPRO® 1 Plus and VPRO® maX: 3 to 9.1 pounds STERIS V-PRO® 60: 3 to 12 pounds STERIZONE® VP4: 3 to 25 pounds	
Models/ Dimensions	12 in×12 in, 15 in×15 in, 18 in×18 in, 20 in×20 in, 24 in×24 in, 36 in×36 in, 45 in×45 in ,48 in×48 in	12 in×12 in, 15 in×15 in, 18 in×18 in, 20 in×20 in, 24 in×24 in, 30 in×30 in, 36 in×36 in, 40 in×40 in, 45 in×45 in, 48 in×48 in,54 in×54 in, 60 in×60 in, 54 in×72 in, 54 in×90 in	Analyze 5
Product Shelf life	I year	Not obtained	Analyze 6
Maintenance of Sterility	365 days	365 days	SAME

Analyze 1

Proposed Device (Sterilization Wrap) is intended to be used to enclose another medical device that is to be sterilized by a health care providerusing:

100% ethylene oxide (EO) with a concentration of 725 - 735mg/l at 131°F/55°C and 40%-80% relative humidity for 60 minutes.

The Predicate Device allow more sterilize method. But the sterilize method of the Predicate Device includes the sterilize method of Proposed Device. And they are all intended to allow sterilization of the enclosed medical device(s) and to maintain sterility of the enclosed device(s) until used.

In addition, the proposed Device has been validated for sterilant Penetration and Sterilization Efficacy in accordance with ANSI AAMI ISO 11135:2014,The result show Negative for growth， Maintenance of package sterility meet requirement.

So, it could be considered as the proposed device has same intend use with equivalent device.

Analyze 2

The product design are similar, the structure is divided into double layer wrap and single layer wrap, the material are all SMS fabric .Double Layer wrap have been ultrasonically sealed on two opposing edges. The design of the Predicate Device includes our device. The difference is that the color of the Dual Layer swap is different.

Proposed Device was tested for package integrity and biocompatibility before and after sterilization, and the test results met the requirements, the safety and performance of the product can be ensured. so the color difference does not affect the safety and effectiveness of the device.

Analyze 3：

The dual Layer color of proposed device and predicate device is different. Proposed Device was tested for package integrity and biocompatibility before and after sterilization, and the test results met the requirements, the safety and performance of the product can be ensured. So the color difference does not affect the safety and effectiveness of the device.

Analyze 4

There are more sterilization methods for Predicate Device, but the sterilization methods including the sterilization method of Proposed Device -EO sterilization, Proposed Device has been validated for sterilant Penetration and Sterilization Efficacy in accordance with ANSI AAMI ISO 11135:2014,The result show Negative for growth，Maintenance of package sterility meet requirement. the safety and performance of the product can be ensured. So the difference does not affect the safety and effectiveness of the device.

Analyze 5

The Dimensions of Proposed Device are included in the Predicate Device Dimensions. Dimensions meet ISO 11607:2019, therefore, this difference will not affect the substantially equivalency.

Analyze 6

The Shelf life 1 year of proposed device has been verified in accordance with ASTM F 1980. After 1 year of accelerated aging, the proposed device performance meets the requirements and has no significant change from 0 year's test results, the safety and performance of the proposed device can be ensured.

Conclusion:

According to the above analysis，our device has minor different from the predicate device, but the difference does not affect the safety and effectiveness of the device. So, the proposed device is determined to be substantially equivalency with predicate device.

Table 2 Performance Comparison

ITEM	Acceptance criteria	**Proposed Device**	**Predicate Device (K181174)**	**Remark**
Sterilant Penetration and Sterilization Efficacy	Achieving a 10^{-6} sterility assurance level	Negative for growth	Negative for growth	SAME
Maintenance of package sterility	Maintain sterility for up to 365 Days	Negative for growth	Negative for growth	SAME
Residuals	Meet ISO 10993-7,	Meet ISO 10993-7	Meet ISO 10993-7	SAME
Biocompatibility	Meet ISO 10993	Meet ISO 10993	Meet ISO 10993	SAME

Material Compatibility, ASTM F2101-19，Bacterial Filtration Efficiency ASTM D5034-09 (2017)，Tensile Strength ASTM D3786/ D3786M -18，Bursting Strength AATCC 127-2018, Water Resistance: Hydrostatic Pressure Test ASTM D737-18, Air Permeability ASTM D3776/ D3776M-20，Mass per Unit Area ASTM D5587-15 (2019)，Tearing Strength, DIN 58953-6: 2016，Microbial Barrier Test	Compatible to EO sterilization process	Compatible	Compatible	SAME

8. Performance data

8.1 Physical properties testing

Item	Standards	Acceptance criteria	Before EO sterilization result	After EO sterilization result	Results summary
-Tensile Strength	ASTM D 5034 -09 (2017)	Complies with the selected physical properties	Passed	Passed	The physical properties testing of before and after EO sterilization meet the acceptance criteria and demonstrated passing results.
-Bursting Strength	ASTM D3786/D3786M-18		Passed	Passed	
-Water Resistance Hydrostatic Pressure Test	AATC127-18		Passed	Passed	
- Air permeability	ASTM D737-18		Passed	Passed	
-Mass per Unit Area	ASTMD37776/D3776M-20		Passed	Passed	
- Tearing strength	ASTM D5587-15		Passed	Passed	
-Dimension	ISO 11607:2019		Passed	Passed	
- lint generation testing	EN 13795-1:2019	Coefficient of linting $\log_{10} \leq 4.0$	≤4.0	≤4.0	

8.2 Sterilization Validation

Item	Standards	Acceptance criteria	Test Result	Results summary
EO Sterilization Validation	ANSI AAMI ISO 11135:2014	Achieving a 10^{-6} sterility assurance level	Negative for growth	Pass
Residuals	ISO 10993-7:2008	Meet ISO 10993-7:2008	None detected	Pass

365 Days Maintenance of Sterility Validation -EO Sterilization	AATCC 127-18 ASTM F 2101-19 ASTM D 5034 -09 (2017) ASTM D3786/D3786M-18 AATC127-18 ASTM D737-18 ASTMD37776/D3776M-20	Maintain sterility for up to 365 Days	Negative for growth, Sterilization Wrap was capable of maintenance of sterility for 365 days.	Pass
	ASTM D5587-15 ISO 11607:2019			
Microbial barrier test	ISO 11607:2019	Product has good anti-bacterial permeability of the packaging material in the microbial barrier test.	Negative for growth	Pass

8.3 Shelf Life Testing

Item	Standards	Acceptance criteria	Test Result	Results summary
Shelf Life Testing	ASTM F 2101-19 ASTM D 5034 -09 (2017) ASTM D3786/D3786M-18 AATC127-18 ASTM D737-18 ASTMD37776/D3776M-20 ASTM D5587-15 ISO 11607:2019	Shelf Life 1 year.	After 1 year of accelerated aging, the proposed device performance meets the requirements and has no significant change from 0 year's test results.	Passed

8.4 Biocompatibility Testing

Item	Standards	Acceptance criteria	Before EO sterilization result	After EO sterilization result	Results summary
Cytotoxicity	ISO 10993-5：2009	Non-cytotoxic	Non-cytotoxic	Non-cytotoxic	Pass
Irritation	ISO 10993-10:2010	Non-irritant	Non-irritant	Non-irritant	Pass
Sensitization	ISO 10993-10:2010	Non-sensitizer	Non-sensitizer	Non-sensitizer	Pass

9. Non-Clinical Test Conclusion

Non clinical tests were conducted to verify that the proposed device met all design specifications as was Substantially Equivalent (SE) to the predicate device. The test results demonstrated that the proposed device complies with the following standards:

- ANSI AAMI ISO 11135:2014 Sterilization of health care products - Ethylene oxide - Requirements for development, validation and routine control of a sterilization process for medical devices.
- ISO 10993-5: 2009 Biological Evaluation Of Medical Devices -- Part 5: Tests For In Vitro Cytotoxicity
- ISO 10993-10: 2010 Biological Evaluation Of Medical Devices - Part 10: Tests For Irritation And Skin Sensitization.
- ISO 10993-7:2008 Biological evaluation of medical devices - Part 7: Ethylene oxide sterilization residuals
- AATCC 127-18 Test Method for Water Resisitance: Hydrostatic Pressure
- ISO 11607:2019 Packaging for terminally sterilized medical devices
- ASTM D5587-15 Standard Test Method for Tearing Strength of Fabrics by Trapezoid Procedure
- ASTM D5034-09 Standard Test Method for Breaking Strength and Elongation of Textile Fabrics (Grab Test)
- ASTM D737-18 Standard test method for air permeability
- ASTM D3776/D3776M Standard test method for mass per unit area (weight) of fabric
- ASTM D3786/D3786M-18 Standard test method for Bursting Strength of Textile Fabrics-Diaphragm Bursting Strength Tester Method
- ASTM F2101-19 Standard Test Method for Evaluating the Bacterial Filtration Efficiency (BFE) of Medical Face Mask Materials, Using a Biological Aerosol of Staphylococcus aureus
- United States Pharmacopeia < 71 >
- EN 13795-1:2019 Surgical clothing and drapes- Requirements and test methods. Part 1:Surgical drapes and gowns

10. Clinical Test Conclusion

No clinical study is included in this submission.

11. Conclusion

Based on the nonclinical tests performed, the subject device is as safe, as effective, and performs as well as or better than the legally marketed predicate device, Cardinal Health TM Sterilization Wrap cleared under K181174.