Wuhan Zonsen Medical Products Co., Ltd.
Linna Ye
Registration Manager
No 8 Jinchao Rd, Zhucheng Street
Wuhan, Hubei
China

August 25, 2023

Re: K223600
Trade/Device Name: Sterilization Wrap
Regulation Number: 21 CFR 880.6850
Regulation Name: Sterilization Wrap
Regulatory Class: Class II
Product Code: FRG
Dated: July 7, 2023
Received: July 21, 2023

Dear Linna Ye:

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: 2023.08.25 13:20:06 -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)*
K223600

Device Name
Sterilization Wrap

Indications for Use *(Describe)*

Sterilization Wrap is intended to be used to enclose another medical device that is to be sterilized by a healthcare provider via the following:

A) Pre-vacuum Steam: 134°C for 4 minutes, 30 minutes dry time.
B) Ethylene Oxide Sterilization: 100% Ethylene Oxide (EO) with a concentration of 360-363 mg/L @ 54°C and 40% relative humidity for 480 minutes, 24 hours aeration time at 42 ºC

Model: ZSW1610, ZSW 1611.
Material: 45gms SMS, 54gms SMS.
Color of wrap: Pink/Blue (double layers).
Size (inches): 12*12, 15*15, 18*18, 20*20, 24*24, 30*30, 36*36, 40*40, 45*45, 48*48, 54*54, 72*54.

The wrap is intended to allow sterilization of the enclosed medical device(s) and maintain sterility of the enclosed device(s) up to 90 days post sterilization.

Types of medical devices to be sterilized in the Pre-Vacuum Steam Sterilization and Ethylene Oxide Sterilization: General purpose non-lumened reusable metal and nonmetal devices including devices with stainless steel diffusionr estricted spaces such as the hinged portion of forceps and scissors, as well as other general medical instruments etc. Models validated for both sterilization methods with stainless steel as part of the load, which with a maximum weight of each types, range from 2lbs to 9lbs, which dependent on each model's size.
For size2*12, 15*15, 18*18, maximum weight is 2lb, for 20*20, 24*24, 30*30, 36*36, 40*40, 45*45, 48*48, maximum weight is 6lb, and for 54*54, 72*54, maximum weight is 9lb.

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.

510(K) Summary

510 (K) Summary

This 510(K) Summary of safety and effectiveness information is being submitted in accordance with requirement of 21 CFR807.92

1. **Date of Submission: August, 23, 2023.**
2. **Submitter / 510(K) Holder**

Wuhan Zonsen Medical Products Co., Ltd.

No. 8 Jinchao Road, Zhucheng Avenue, Xinzhou District, Wuhan City, Hubei Province, P.R. China 431400

Contact Person: Ms. Lisa Zhang

Position: Registration Manager

Email: registration01@zonsenmed.com

3. **Proposed Device Name**

Trade name: Sterilization Wrap

Common name: Sterilization Wrap

Classification Name: Wrap, Sterilization/Indicator, Physical/Chemical Sterilization Process

Device Class: Class II

Classification Panel: General Hospital

Product Code: FRG

Regulation Number: 21 CFR 880.6850

4. **Predicate Devices**

Primary Predicate Device: K160755

Product Name: Reliance® Solo Sterilization Wrap, Reliance® Tandem Sterilization Wrap

Submitter: Ahlstrom Nonwovens LLC

5. Device Description

Sterilization Wrap is square or rectangular three-layer (SMS) non-woven sheet which manufactured with Polypropylene spunbond-meltblown-spunbond (SMS) fabric. Sterilization wrap provides a strong barrier which protects against cuts, tears with particularly device sets. The device is designed to be implemented as an outer sterilization wrap which allow sterilization of the enclosed medical device(s) and maintain sterility of the enclosed device(s) up to 90 days post Pre-Vacuum Steam Sterilization or Ethylene Oxide Sterilization.

Sterilization Wrap is two-layer sheet which ultrasonically bonded blue and pink non-woven sheet together along two edges, thus for convenient simultaneous wrapping.

Sterilization Wrap separated into two distinct types depending on different grams of weight of material, for ZSW 1610, it is two 45gsm SMS non-woven sheet ultrasonically bonded together, and for model ZSW 1611, it is two 54gsm SMS sheet. Each model contains series specification, including 12 Sizes (inches): 12*12, 15*15, 18*18, 20*20, 24*24, 30*30, 36*36, 40*40, 45*45, 48*48, 54*54, 72*54. With non-lumened reusable metal and nonmetal devices as part of the load, which with a maximum weight of each type, range from 2lbs to 9lbs, which dependent on each model' size (table 1)

Table 1 Device Specification

Model	Material	Layers	Color	Size		Maximum Weight(lbs.)
				Long (inches)	Width (inches)	
ZSW1610	45 gsm SMS	2	Pink and Blue double layers	12	12	2
				15	15	2
				18	18	2
				20	20	6
				24	24	6
				30	30	6
				36	36	6

				40	40	6
				45	45	6
				48	48	6
				54	54	9
				72	54	9
ZSW1611	54 gsm SMS	2	Pink and Blue double layers	12	12	2
				15	15	2
				18	18	2
				20	20	6
				24	24	6
				30	30	6
				36	36	6
				40	40	6
				45	45	6
				48	48	6
				54	54	9
				72	54	9

6. Indications for Use

Sterilization Wrap is intended to be used to enclose another medical device that is to be sterilized by a healthcare provider via the following:

A) Pre-vacuum Steam: 134°C for 4 minutes, 30 minutes dry time.

B) Ethylene Oxide Sterilization: 100% Ethylene Oxide (EO) with a concentration of 360~363 mg/L @ 54°C and 40% relative humidity for 480 minutes, 24 hours aeration time at 42 ºC.

Model: ZSW1610, ZSW 1611.

Material (single layer): 45gms SMS, 54gms SMS.

Color of wrap: Pink/Blue.

Size (inches): 12*12, 15*15, 18*18, 20*20, 24*24, 30*30, 36*36, 40*40, 45*45, 48*48, 54*54, 72*54.

The wrap is intended to allow sterilization of the enclosed medical device(s) and maintain sterility of the enclosed device(s) up to 90 days post sterilization.

Types of medical devices to be sterilized in the Pre-Vacuum Steam Sterilization and Ethylene Oxide Sterilization:

General purpose non-lumened reusable metal and nonmetal devices including devices with stainless steel diffusionr estricted spaces such as the hinged portion of forceps and scissors, as well as other general medical instruments etc.

Models validated for both sterilization methods with stainless steel as part of the load, which with a maximum weight of each type, range from 2lbs to 9lbs, which dependent on each model's size.

For size：2*12, 15*15, 18*18, maximum weight is 2lb, for 20*20, 24*24, 30*30, 36*36, 40*40, 45*45, 48*48, maximum weight is 6lb, and for 54*54, 72*54, maximum weight is 9lb.

7. Technological Characteristics Comparison Table

The Sterilization Wrap is compared with the predicate device Reliance® Solo Sterilization Wrap, Reliance® Tandem Sterilization Wrap (K160755). The results are shown below in the Technological Characteristics Comparison Table:

Table 2 General Comparison between proposed and predicate device

Device characteristic	**Proposed Device**	**Predicate Device 510(K) No. K160755**	**Comparison Result**
Manufacturer	Wuhan Zonsen Medical Products Co., Ltd.	Ahlstrom Nonwovens, LLC	--
Product name	Sterilization wrap	Reliance® Solo Sterilization Wrap, Reliance® Tandem Sterilization Wrap	--
510(k) Reference	K223600	K160755	--

Class	Class II	Class II	Same
Product Code	FRG	FRG	Same
Regulation Number	21 CFR PART 880.6850	21 CFR PART 880.6850	Same
Intended Use	Sterilization Wrap is intended to be used to enclose another medical device that is to be sterilized by a healthcare provider.	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.	Same
Indication for use	Sterilization Wrap is intended to be used to enclose another medical device that is to be sterilized by a healthcare provider via the following: Pre-vacuum Steam: 134°C for 4 minutes, 30 minutes dry time. B) 100% Ethylene Oxide (EO) with a concentration of 360~363 mg/L @ 54°C and 40% relative humidity for 480 minutes, 24 hours aeration time at 42 ºC.	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: A) 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, Validated for dry time of 30 minutes for Models T400/S400, T500/S500, T600/S600.	Similar

		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. C) Gravity Steam 250°F/121°C for 30 minutes D)Advanced Sterilization Products (ASP) STERRAD® 100S E) Advanced Sterilization Products (ASP) STERRAD® 100NX (Standard, Express and Flex cycles) F) 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) up to 90	The wrap is intended to allow sterilization of the enclosed medical device(s) and maintain sterility of the enclosed	Similar

	days post sterilization.	device(s) until used.	
Material Composition	Polypropylene spunbondmeltblown-spunbond (SMS) fabric	Polypropylene spunbondmeltblown-spunbond (SMS) fabric	Same
Design feature	Zonsen Sterilization Wrap is square or rectangular three-layer (SMS) non-woven sheet which manufactured with Polypropylene spunbond-meltblown-spunbond (SMS) fabric. The device has two-layer sheet which ultrasonically bonded blue and pink non-woven sheet together along two edges, thus for convenient simultaneous wrapping.	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® 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. Reliance® Tandem: Consists of single sheets	Same

		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.	
Size and color	Pink and blue Sterilization Wrap separated into two distinct types depending on different grams of weight of material, Size (inches): 12*12, 15*15, 18*18, 20*20, 24*24, 30*30, 36*36, 40*40, 45*45, 48*48, 54*54, 72*54.	Blue and green Dimensional Specifications of Reliance® Tandem and Reliance® Solo Wrap: six type Models depend on various grams of weight, Size (inches): 9*9, 12*12, 15*15, 18*18, 20*20, 24*24, 30*30, 36*36, 40*40, 45*45, 48*48, 54*54, 60*60, 72*54.	Similar
Single Use vs. Reusable	Single use	Single use	Same
Disposable vs. Non-Disposable	Disposable	Disposable	Same
Maximum Recommended Wrapped Package	Types of medical devices to be sterilized in the Pre-Vacuum Steam Sterilization	All models of Reliance® Tandem and Solo validated for pre-vacuum	Similar

Content Weights	and Ethylene Oxide Sterilization: General purpose non-lumened reusable metal and nonmetal devices including devices with stainless steel diffusionr estricted spaces such as the hinged portion of forceps and scissors, as well as other general medical instruments etc. Models validated for both sterilization methods with stainless steel as part of the load, which with a maximum weight of each type, range from 2lbs to 9lbs, which dependent on each model's size.	steam Sterilization and 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.	
Size and Gram weight	ASTM D3776/ D3776M-20 Size: Marking dimension tolerance ±10%; Weight : Marking gram tolerance ±2g/m2 the inspection result is PASS	ASTM D3776/ D3776M-20 Size: Marking dimension tolerance ±10%; Weight : Marking gram tolerance ±2g/m2 the inspection result is PASS	Same
Bacterial Filtration Efficiency (BFE)	ASTM F2101-19 Bacterial Filtration Efficiency (BFE) Using a Biological Aerosol	ASTM F2101-19 Bacterial Filtration Efficiency (BFE) Using a	Same

	of Staphylococcus aureus ≥ 90% the inspection result is PASS	Biological Aerosol of Staphylococcus aureus ≥ 90% the inspection result is PASS	
Hydrostatic Pressure	AATCC 127-03, Water Resistance: Hydrostatic Pressure ≥ 50 cm H2O the inspection result is PASS	AATCC 127-03, Water Resistance: Hydrostatic Pressure ≥ 50 cm H2O the inspection result is PASS	Same
Tensile Strength	ASTM D5034-09 Standard, Breaking Strength and Elongation of Textile Fabrics (Grab Test) MD≥ 90N; CD≥ 63N the inspection result is PASS	ASTM D5034-09 Standard, Breaking Strength and Elongation of Textile Fabrics (Grab Test) MD≥ 90N; CD≥ 63N the inspection result is PASS	Same
Air Permeability	ASTM D737-18Standard, Air Permeability of Textile Fabrics ≥ 30 cfm the inspection result is PASS	ASTM D737-18Standard, Air Permeability of Textile Fabrics ≥ 30 cfm the inspection result is PASS	Same
Bursting Strength	ASTM D3786-18 Standard Test Method for Bursting Strength of Textile Fabrics—Diaphragm Bursting Strength Tester Method ≥ 130 kpa (18.86psi) the inspection result is	ASTM D3786-18 Standard Test Method for Bursting Strength of Textile Fabrics—Diaphragm Bursting Strength Tester Method ≥ 130 kpa (18.86psi) the inspection result is	Same

	PASS	PASS	
Tearing Strength	ASTM D5587-15, Tearing Strength of Fabrics, MD≥ 50N, CD≥ 30N. the inspection result is PASS	ASTM D5587-15, Tearing Strength of Fabrics, MD≥ 50N, CD≥ 30N. the inspection result is PASS	Same
Lint Generation	ISO9073-10, Textiles Lint, Cofficient of linting ≤4.0 the inspection result is PASS	ISO9073-10, Textiles Lint, Cofficient of linting ≤4.0 the inspection result is PASS	Same
Material Compatibility	After Pre-vacuum Steam or 100% Ethylene Oxide (EO) sterilization, the materials were not degraded. Performance test including Size and Gram weight Bacterial Filtration Efficiency (BFE) Hydrostatic Pressure Tensile Strength Air Permeability Bursting Strength Tearing Strength Lint Generation can meet requirements	After Pre-vacuum Steam or 100% Ethylene Oxide (EO) sterilization, the materials were not degraded. Performance test including Size and Gram weight Bacterial Filtration Efficiency (BFE) Hydrostatic Pressure Tensile Strength Air Permeability Bursting Strength Tearing Strength Lint Generation can meet requirements	Same
Biocompatibility	ISO 10993-5 non-cytotoxic post sterilization	ISO 10993-5, non-cytotoxic post	Same

		sterilization	
Maintenance of Sterility	90days	90days	Same
Shelf Life	2 years from date of manufacture	unknown	Similar

The design and technological characteristics of the Sterilization wrap is similar to the predicate chosen. There are minor differences between the devices including Indication for use (sterilization parameter), Size and color, Maximum Recommended Wrapped Package Content Weights,

Note 1： Indication for use (sterilization parameter)

The proposed device and the predicate device have same sterilizaiton method application, including Pre-vacuum Steam or 100% Ethylene Oxide (EO) sterilization. For those two devices, parameter recommend are different. However, the proposed device has been conducted verification in accordance with ISO11135 and ISO 17665, performance test has been done before and after sterilizaiton, all results can meet standards requirements. Therefore, there are no different questions of safety and effectiveness questions pertaining to performance of the proposed device.

Note 2： Size and color

The proposed device and the predicate device have same dimention, but they are differences in color. However, the proposed device meets the requirements of the standard ISO 10993-5, articles after the steam and EO sterilized were used for the biocompatibility validation testing. Test result shows that the device has non-cytotoxicity. Therefore, the different technological specifications of the proposed device do not raise different questions of safety.

Note 3 Maximum Recommended Wrapped Package Content Weights

Although the maximum recommended wrap package loading are different from the predicate device,the proposed device has been conducted verification in accordance with ISO11135 and ISO 17665, Types of medical devices to be sterilized in the Pre-Vacuum

Steam Sterilization and Ethylene Oxide Sterilization including general purpose non-lumened reusable metal and nonmetal devices including devices with stainless steel diffusionr estricted spaces such as the hinged portion of forceps and scissors, as well as other general medical instruments etc. All models validated for both sterilization methods with stainless steel as part of the load, which with a maximum weight of each types, range from 2lbs to 9lbs, which dependent on each model's size.

Performance test has been done before and after sterilizaiton, all results can meet standards requirements. Therefore, there are no different questions of safety and effectiveness questions pertaining to performance of the proposed device.

Note 4 Performance test

Both the predicate device and the proposed device has been tested including, Size and Gram weight, Bacterial Filtration Efficiency (BFE), Hydrostatic Pressure, Tensile Strength, Air Permeability, Bursting Strength, Tearing Strength, Lint Generation. Result shows that there are no different questions of safety and effectiveness questions related to performance.

Based on above analysis mentioned above, we can conclude that subject device substantial equivalence with the predicate device.

8. Performance Data

Non-Clinical Performance Test Conclusion

Non-clinical tests were conducted to verify that the proposed device met all design specifications was Substantially Equivalent (SE) to the predicate Sterilization Wraps complies with the following standards:

Test Items	Standard and Acceptance Criteria	Test Result
Size and Gram weight	ASTM D3776M-20: Standard Test Methods for Mass Per Unit Area (Weight) of Fabric Size : Marking dimension tolerance ±10%; Weight : Marking gram tolerance ±2g/m^2	Pass
Bacterial	ASTM F 2101- 19 Standard Test Method for Evaluating	Pass

Filtration Efficiency (BFE)	the Bacterial Filtration Efficiency (BFE) of Medical Face Mask Materials, Using a Biological Aerosol of Staphylococcus aureus BFE ≥ 90%	
Hydrostatic Pressure	AATCC 127-03 Test Method for Water Resistance: Hydrostatic Pressure Hydrostatic Pressure ≥ 50 cm H_2O	Pass
Tensile Strength	ASTM D5034-09 Standard Test Method for Breaking Strength and Elongation of Textile Fabrics (Grab Test) MD≥ 90N; CD≥ 63N	Pass
Air Permeability	ASTM D737-18Standard Test Method for Air Permeability of Textile Fabrics Air Permeability≥ 30 cfm	Pass
Bursting Strength	ASTM D3786-18 Standard Test Method for Bursting Strength of Textile Fabrics—Diaphragm Bursting Strength Tester Method Bursting Strength≥ 130 kpa (18.86psi)	Pass
Tearing Strength	ASTM D5587-15 Standard Test Method for Tearing Strength of Fabrics by Trapezoid Procedure MD≥ 50N; CD≥ 30N	Pass
Lint Generation	ISO9073-10: 2019 Textiles — Test methods for nonwovens — Part 10: Lint and other particles generation in the dry state Coefficient of linting ≤4.0	Pass
Skin Irritation AND Skin Sensitization	ISO 10993- 1 Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process. ISO 10993-5 Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity of medical devices. ISO 10993-10:2010 Biological Evaluation of Medical Devices – Part 10: Tests for irritation and skin sensitization. Under the conditions of the study, the test article (pouches	Pass

	and chemical indicator) extract did not show no significant evidence of causing skin sensitization in the guinea pig before and after sterilized.	
Shelf-Life Validation	Shelf Life Validation Test; Conducted the shelf-life testing as real time aging method. After the shelf life indicated as following, Shelf Life: 2 Years; Shelf Life after Sterilized: 90 days; The device performance shall be meet the requirements of the device. SAL=10^{-6}	Pass
Sterilization Process Validation for EO	EO Sterilization Process Validation Test. Conducted the EO sterilization process validation as the method/principle of ISO11135: 2014 Sterilization of health care products - Ethylene oxide - Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices (Healthcare Product Sterilization - Ethylene Oxide-Medical Device Sterilization Process Development. Validation and Routine Control Requirements). Use the half cycle method to validate the EO sterilization cycle claimed in indication for use is effective. Ethylene Oxide Sterilization: 100% Ethylene Oxide (EO) with a concentration of 360-363 mg/L @ 54°C and 40% relative humidity for 480 minutes, 24 hours aeration time at 42 ºC The device performance shall be meet the requirements of the device with the worst loading, SAL=10^{-6}	Pass

Sterilization Process Validation for steam	Steam Sterilization Process Validation Test. Conducted the Steam sterilization process validation as the method/principle of AAMI / ANSI ST79: 2010 & A1:2010 & A2:2011 & A3:2012 & A4:2013, Comprehensive Guide To Steam Sterilization And Sterility Assurance In Health Care Facilities and ISO 17665- 1:2006 Sterilization of health care products Moist heat Part 1: Requirements for the development, validation and routine control of a sterilization process for medical devices 's requirements. Pre-vacuum Steam: 134°C for 4 minutes, 30 minutes dry time. The device performance shall be meet the requirements of the device with the worst loading, SAL=10^{-6}	Pass
Material compatibility	After Pre-vacuum Steam or 100% Ethylene Oxide (EO) sterilization, the materials were not degraded. Performance test including: Size and Gram weight Bacterial Filtration Efficiency (BFE) Hydrostatic Pressure Tensile Strength Air Permeability Bursting Strength Tearing Strength Lint Generation should meet requirements.	Pass
EO/ECH residue	ISO 10993-7: 2008 Biological evaluation of medical devices — Part 7: Ethylene oxide sterilization residuals EO≤4mg/d, ECH ⩽9mg/d	Pass

Non-clinical tests including physical characteristics shown in table above, shelf life validation, biocompatibility evaluation, EO Sterilization Process Validation and Steam

Sterilization Process Validation has been taken to shown all results can meet the standards. Aged device were used for material compatibility research, after Pre-vacuum Steam or 100% Ethylene Oxide (EO) sterilization, the materials were not degraded and all physical characteristics test result can still meet requirements.

Clinical Test Conclusion

No clinical study is included in this submission.

9. Conclusion

The conclusions drawn from the non-clinical tests demonstrate that the proposed device is as safe, as effective, and performs as well as the predicate device K160755.