February 13, 2023

Qianjiang Kingphar Medical Packaging & Printing Co., Ltd.
% Boyle Wang
Official Correspondent
Shanghai Truthful Information Technology Co., Ltd.
RM.1801, No.161, East Lujiazui Rd., Pudong
Shanghai, Shanghai 200120
China

Re: K221875
Trade/Device Name: Sterilization Pouch and Roll
Regulation Number: 21 CFR 880.6850
Regulation Name: Sterilization Wrap
Regulatory Class: Class II
Product Code: FRG, JOJ
Dated: January 17, 2023
Received: January 17, 2023

Dear Boyle 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,

Anne D. Talley -S 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)*
K221875

Device Name
Sterilization Pouch and Roll

Indications for Use *(Describe)*
The Sterilization Pouch and Roll are intended to provide health care workers with an effective method to enclose devices intended for sterilization in the Steam or via Ethylene Oxide (EO). The recommended sterilization cycles are as follows:
• Steam Sterilization at 132°C (270°F) for 4 minutes; Drying time of 20 minutes.
• Ethylene Oxide (EO) with a concentration of 800 mg/L at 55°C (131°F) and 40% to 90% relative humidity for 6 hour. Aeration time of 7 days at 20°C).

The sterilization pouch and roll are made with medical grade paper and medical compound film.The sterilization pouch and roll maintains the sterility of the enclosed devices for up to 24 months post Steam or EO gas sterilization, and before sterilization has a maximum shelf life of 5 years from the date of manufacture.
The pouch's external chemical ink indicators are designed to indicate to the user that the pouch has undergone either a steam or EO sterilization process. Sterilization indicator will change color according to the sterilization method (ethylene oxide, steam). Ethylene oxide sterilization indicator color change from pink before sterilization to yellow after sterilization. The steam sterilization indicator color change from blue before sterilization to dark grey after sterilization.

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 maximum validated pouch load is 1.1 lbs (0.5kg); The maximum validated roll load is 1.1 lbs (0.5kg).

(Model and Dimension and Content/Max. Load)

Model	Item	Specification Size (WXL)		Content/Max Load(lbs)		
	NO.	Inch	mm*mm	Metal	Plastic	Gauze/Linens
PLANE-01 Sterilization Pouch	P-001	2.25"x3.5"	57x90	0.02	0.01	0.003
	P-002	2.25"x4"	57x100	0.03	0.02	0.004
	P-003	2.25"x5"	57x130	0.04	0.03	0.005
	P-004	2.75"x10"	70x260	0.09	0.08	0.07
	P-005	3.5"x5.25"	90x135	0.10	0.09	0.08
	P-006	3.5"x6.5"	90x165	0.12	0.11	0.1
	P-007	3.5"x10"	90x260	0.14	0.13	0.11
	P-008	51/3"x10"	135x260	0.48	0.46	0.45
	P-009	51/3"x11	135x280	0.50	0.47	0.46
	P-010	51/3"x13"	135x330	0.55	0.53	0.50
	P-011	7.5"x14"	190x360	0.60	0.58	0.55
	P-012	10"x14.5"	250x370	1.06	1.05	0.62
	P-013	10.25"x16"	260x410	1.08	1.07	0.64
	P-014	12"x17.7"	300x450	1.10	1.09	0.66
ROLL-01 Sterilization Roll	R-101	2”	50mm×200m	0.02	0.01	0.003
	R-102	3”	75mm×200m	0.09	0.05	0.004
	R-103	4”	100mm×200m	0.14	0.13	0.11
	R-104	6”	150mm×200m	0.55	0.53	0.50
	R-105	8”	200mm×200m	0.60	0.58	0.55
	R-106	10’	250mm×200m	1.06	1.05	0.62
	R-107	12”	300mm×200m	0.60	0.58	0.55
	R-108	14”	350mm×200m	1.06	1.05	0.62
	R-109	16”	400mm×200m	1.08	1.07	0.64
	R-110	17.7”	450mm×200m	1.10	1.09	0.66
	R-111	20”	500mm×200m	1.10	1.09	0.66
	GR-201	3”	75mm×100m	0.09	0.05	0.004
	GR-202	4”	100mm×100m	0.14	0.13	0.11
	GR-203	6”	150mm×100m	0.55	0.53	0.50
	GR-204	8”	200mm×100m	0.60	0.58	0.55
	GR-205	10”	250mm×100m	1.06	1.05	0.62
	GR-206	12”	300mm×100m	0.60	0.58	0.55
	GR-207	14”	350mm×100m	1.06	1.05	0.62
	GR-208	16”	400mm×100m	1.08	1.07	0.64

510(k) Summary

K221875

This summary of 510(k) safety and effectiveness information is being submitted in accordance with requirements of 21 CFR 807.92.

1.0 Submitter's Information

Name: Qianjiang Kingphar Medical Packaging & Printing Co., Ltd.
Address: Dongjing Road 23, Yuanlin Office,433100 Qianjiang, PEOPLE'S REPUBLIC OF CHINA
Tel: +86-13349816939
Contact: Zhao Fusong

Designated Submission Correspondent

Contact: Mr. Boyle Wang
Name: Shanghai Truthful Information Technology Co., Ltd.
Address: Room 1801, No. 161 East Lujiazui Rd., Pudong Shanghai, 200120 China
Tel: +86-21-50313932
Email: Info@truthful.com.cn

Date Submitted: Feb.11,2023

2.0 Device Information

Trade/Device name: Sterilization Pouch and Roll
Common name: Sterilization Pouch and Roll
Regulation Name: 1) Sterilization Wrap;
2) Sterilization process indicator
Classification Product Code: 1) FRG;
Subsequent Product Code: 2) JOJ
Regulation number: 1) 21 CFR880.6850
2) 21 CFR880.2800
Classification: Class II
Panel: General Hospital

3.0 Predicate Device Information

Predicate Device:

Manufacturer: Sterileright Packaging Mfg., Inc
Trade/Device Name: SterileRight Sterilization Pouch and Roll
510(k) number: K212338

Reference Device:
Manufacturer: Sigma Medical Supplies Corp.
Trade/Device Name: SIGMA Sterilization Pouch and Roll
510(k) number: K180661

4.0 Device Description

The Sterilization pouch and roll is composed of medical grade paper(60g/m^2) and medical compound film(52μm), it is intended to be used to contain medical devices to be terminally sterilized by the EtO or Steam sterilization process. The recommended sterilization cycle parameter is:
Steam: 4 minutes at 132°C (270°F); 20 minutes dry time.
Ethylene oxide: 6 hours at 55 ºC; relative humidity between 40%- 90%; ethylene oxide concentration is 800 mg/L, 7 days aeration time at 20 ºC.

The medical devices are inserted into the Pouch/Roll, sealed, and then sterilized for the EtO or Steam Sterilization Process. The heat-sealed pouch/roll are heat sealed prior to sterilization processing. After completion of the sterilization process, the Pouch/Roll maintain sterility of the enclosed medical devices until the seal is opened.

The device is intended to allow sterilization of enclosed devices and also to maintain sterility of the enclosed devices until used up to 24 months post sterilization.

The Pouch/Roll is printed with a chemical indicator bar that changes from Pink to Yellow (EtO) or Blue to Dark grey (Steam) when exposed to EtO gas or Steam vapor during process. The EtO and Steam Chemical Indicator offers an addition way to verity processing in the sterilization cycle. The Chemical Indicator should be used in addition to, not in place of, the biological indicator. The EtO and Steam Chemical Indicators do not signify sterilization; they only indicate that the indicator has been exposed to the EtO or Steam.

5.0 Indication for Use Statement

The Sterilization Pouch and Roll are intended to provide health care workers with an effective method to enclose devices intended for sterilization in the Steam or via Ethylene Oxide (EO). The recommended sterilization cycles are as follows:
- Steam Sterilization at 132°C (270°F) for 4 minutes; Drying time of 20 minutes.
- Ethylene Oxide (EO) with a concentration of 800 mg/L at 55° C (131° F) and 40% to 90% relative humidity for 6 hour. Aeration time of 7 days at 20℃).

The sterilization pouch and roll are made with medical grade paper and medical compound film. The sterilization pouch and roll maintains the sterility of the enclosed devices for up to 24 months post Steam or EO gas sterilization, and before sterilization has a maximum shelf life of 5 years from the date of manufacture.
The pouch's external chemical ink indicators are designed to indicate to the user that the pouch has undergone either a steam or EO sterilization process. Sterilization indicator will change color according to the sterilization method (ethylene oxide, steam). Ethylene oxide sterilization indicator color change from prink before sterilization to yellow after sterilization. The steam sterilization indicator color change from blue before sterilization to dark grey after sterilization.

The maximum validated pouch load is 1.1 lbs (0.5kg); The maximum validated roll load is 1.1 lbs (0.5kg).

(Model and Dimension and Content/Max. Load)

Model	Item	Specification Size (WXL)		Content/Max Load(lbs)		
	No.	Inch	mm*mm	Metal	Plastic	Gauze/Linens
PLANE-01 Sterilization Pouch	P-001	2.25"x3.5"	57x90	0.02	0.01	0.003
	P-002	2.25"x4"	57x100	0.03	0.02	0.004
	P-003	2.25"x5"	57x130	0.04	0.03	0.005
	P-004	2.75"x10"	70x260	0.09	0.08	0.07
	P-005	3.5"x5.25"	90x135	0.10	0.09	0.08
	P-006	3.5"x6.5"	90x165	0.12	0.11	0.1
	P-007	3.5"x10"	90x260	0.14	0.13	0.11
	P-008	51/3"x10"	135x260	0.48	0.46	0.45
	P-009	51/3"x11	135x280	0.50	0.47	0.46
	P-010	51/3"x13"	135x330	0.55	0.53	0.50
	P-011	7.5"x14"	190x360	0.60	0.58	0.55
	P-012	10"x14.5"	250x370	1.06	1.05	0.62
	P-013	10.25"x16"	260x410	1.08	1.07	0.64
	P-014	12"x17.7"	300x450	1.10	1.09	0.66
ROLL-01 Sterilization Roll	R-101	2”	50mm×200m	0.02	0.01	0.003
	R-102	3”	75mm×200m	0.09	0.05	0.004
	R-103	4”	100mm×200m	0.14	0.13	0.11
	R-104	6”	150mm×200m	0.55	0.53	0.50
	R-105	8”	200mm×200m	0.60	0.58	0.55
	R-106	10’	250mm×200m	1.06	1.05	0.62
	R-107	12”	300mm×200m	0.60	0.58	0.55
	R-108	14”	350mm×200m	1.06	1.05	0.62
	R-109	16”	400mm×200m	1.08	1.07	0.64
	R-110	17.7”	450mm×200m	1.10	1.09	0.66

	R-111	20”	500mm×200m	1.10	1.09	0.66
	GR-201	3”	75mm×100m	0.09	0.05	0.004
	GR-202	4”	100mm×100m	0.14	0.13	0.11
	GR-203	6”	150mm×100m	0.55	0.53	0.50
	GR-204	8”	200mm×100m	0.60	0.58	0.55
	GR-205	10”	250mm×100m	1.06	1.05	0.62
	GR-206	12”	300mm×100m	0.60	0.58	0.55
	GR-207	14”	350mm×100m	1.06	1.05	0.62
	GR-208	16”	400mm×100m	1.08	1.07	0.64

6.0 Summary of Non-Clinical Testing

Summary of non-clinical and performance testing bench testing was performed to evaluate the performance and functionality of the subject device against requirement specification. The test results demonstrated the subject device is confirmed to be safe and effective for the intended use.

Table 1: Performance testing summary – Bench

Test Item	Test Methodology	Acceptance Criteria or End Point	Results
Sterilization Process Validation	ISO 11135:2014	Ethylene oxide: 6 hours at 55 ℃; relative humidity between 40%- 90%; ethylene oxide concentration is 800 mg/L, 7days aeration time at 20℃. SAL=10^{-6}	SAL=10^{-6} Pass
	ISO 17665-1:2006; ISO TS 17665-2:2009	Steam; 8 minutes at 134℃; 8 minutes dry time. SAL=10^{-6}	SAL=10^{-6} Pass
EO/ECH Residuals	ISO 10993-7:2008	EO < 4mg ECH < 9mg	Pass
Biocompatibility testing	ISO 10993-5:2009	Non-cytotoxic	Under conditions of the study, did not show potential toxicity to L-929 cells. Pass
	ISO 10993-10:2010	Non-irritating	Under the conditions of the study, not an irritant. Pass
	ISO 10993-10:2010	Non-sensitizing	Under conditions of the study, not a sensitizer. Pass

Package Integrity / Material Compatibility /Sterility Maintenance	ASTM F 2251-13	52μm±12%	Pass
	ASTM F1140/F1140M-13	Burst value > 3 Kpa or No Burst	Minimum of Burst pressure = 6.4 (kPa) Pass
	ASTM F1929-15	The dye solution is no any leakage across the seal width of sterile barrier system. (No Infiltration)	No Infiltration Pass
	ASTM F88/F88M-15	Seal strength > 2.5 (N/15mm)	Minimum of Seal strength = 2.9 Pass
	ISO 1924-2:2008	Tensile strength: CD≧2.2KN/m,MD≧4.4KN/m	Pass
	Real time aging	5 years real time aging Incubation 24 months real time aging Incubation for post steam/EO sterilization storage	The test results of all samples are meet the requirements. Pass
	ASTM F2096-11	No Leakage	No Leakage Pass
	DIN 58953-6	CFU = 0	CFU = 0 Pass
Chemical Indicator Efficacy Testing	ISO 11140-1:2014 Steam: The color of CI changes from Blue to Dark Grey, when exposed to Steam; EO: The color of CI changes from Pink to Yellow, when exposed to EO gas.	Steam Change the color: Color of indicator changes from blue to dark grey after Steam sterilization	Color of indicator changes from blue to dark grey under indicated condition and no changed under other condition. Pass
		EO gas Color of indicator changes from pink to yellow after EO sterilization	Color of indicator changes from pink to yellow under indicated condition and no changed under other condition. Pass

	1. Remain stable before use based on its shelf life. 2. Maintain the endpoint stability of the color change after being in the presence of the sterilant.	All performance attributes should maintain the original color : 5 years shelf life	The real-time test was carried out from Jan. 08, 2020 to Jan.20, 2022 that demonstrates: the test device which exposed to Steam maintain the color of Dark Grey, the test group which exposed to EO maintain the color of Yellow, and the real-time test was carried out on the empty pouch that demonstrates the test device maintain the original color from Jan. 08, 2017 to Jan.28, 2022.

7.0 Technological Characteristic Comparison Table

Table 2- Comparison of Technology Characteristics

Item	Subject Device	Predicate Device	Reference Device	Comparison Analysis
Product Name	**Sterilization Pouch and Roll**	**SterileRight sterilization pouch and roll**	**SIGMA Sterilization Pouch and Roll**	**----**
510(k) No.	K221875	K 212338	K180661	----
Product Code	FRG,JOJ	FRG,JOJ	FRG	Same
Regulation No.	21 CFR 880.6850 21 CFR 880.2800	21 CFR 880.6850 21 CFR 880.2800	21 CFR 880.6850	Same
Class	II	II	II	Same
Intended Use	The Sterilization Pouch and Roll are intended to provide health care workers with an effective method to enclose devices intended for sterilization in the Steam or via Ethylene Oxide (EO). The recommended sterilization cycles are as follows: • Steam Sterilization at 132°C (270°F) for 4 minutes; Drying time of 30 minutes. • Ethylene Oxide (EO) with a	The SterileRight Sterilization Pouch and Roll are intended to provide health care workers with an effective method to enclose devices intended for sterilization in the Steam or via Ethylene Oxide (EO). The recommended sterilization cycles are as follows: • Gravity steam at 121°C (250°F) for 30 minutes; Drying time of 25 minutes.	The SIGMA sterilization pouch and roll are intended to provide health care workers with an effective method to enclose devices intended for sterilization in steam auto claves and via Ethylene Oxide (EO). The recommended steam sterilization cycle parameters are 30 minutes at 121°C. The recommended EO sterilization cycle is 4 hours at 55°C with a relative humidity	Similar

	concentration of 800 mg/L at 55° C (131° F) and 40% to 90% relative humidity for 6 hour. Aeration time of 7 days at 20℃). The sterilization pouch and roll are made with medical grade paper and medical compound film.The sterilization pouch and roll maintains the sterility of the enclosed devices for up to 24 months post Steam or EO gas sterilization, and before sterilization has a maximum shelf life of 5 years from the date of manufacture. The pouch's external chemical ink indicators are designed to indicate to the user that the pouch has undergone either a steam or EO sterilization process. Sterilization indicator will change color according to the sterilization method (ethylene oxide, steam). Ethylene oxide sterilization indicator color change from Prink	• Pre-vacuum steam at 132°C (270°F) for 4 minutes; Drying time of 20 minutes. • Ethylene Oxide (EO) with a concentration of 735 mg/L at 55°C (131°F) and 50% to 80% relative humidity for 60 minutes. Aeration time of 8 hours at 60°C (140°F). The SterileRight provide sterilization pouch and roll made with Paper/Film or Tyvek® /Film. The SterileRight sterilization pouch and roll which are made with Paper maintains the sterility of the enclosed devices for up to 6 months post Steam or EO gas sterilization, and before sterilization has a maximum shelf life of 3 years from the date of manufacture. The pouch's external chemical ink indicators are designed to indicate to the user that the pouch has undergone either a steam or EO sterilization process.	between 50%-85% and a sterilant concentration of 600 mg/L. Furthermore, the sterilization pouch and roll maintains the enclosed devices up until 3 years post EO gas sterilization and maintains the enclosed devices up until 6 months post Steam sterilization. Lastly, the pouch's external chemical ink indicators are designed to indicate to the user that the pouch has undergone either a steam or EO sterilization process. The SIGMA sterilization pouch and roll is offered in the following 5 types: ● Self-sealing sterilization pouches ●Sterilization pouches, Flat ● Sterilization pouches, Gusseted ●Sterilization rolls, Flat ●Sterilization rolls, Gusseted	

	before sterilization to Yellow after sterilization. The steam sterilization indicator color change from Blue before sterilization to Dark Grey after sterilization.	The SterileRight sterilization pouch and roll which are made with Tyvek® is for EO gas sterilization only. It also maintains the sterility of the enclosed devices for up to 6 months post EO gas sterilization, and before sterilization has a maximum shelf life of 3 years from the date of manufacture.		
Material Composition	Composed of medical grade paper and medical compound film, EO and Steam Process Indicator	Medical Grade Paper, CPP, PET, adhesive,EO and Steam Process Indicator, Print Ink. Tyvek® , PET, PE, adhesive.	Medical Grade Paper, CPP, PET, PU adhesive, EO and Steam Process Indicator Print Ink	Same
Sterilization Cycles	• Steam Sterilization at 132°C (270°F) for 4 minutes; Drying time of 20 minutes. • Ethylene Oxide (EO) with a concentration of 800 mg/L at 55°C (131°F) and 40% to 90% relative humidity for 6 hour. Aeration time of 7 days at 20℃).	•Gravity steam at 121°C (250°F) for 30 minutes; Drying time of 25 minutes. • Pre-vacuum steam at 132°C (270°F) for4 minutes; Drying time of 20 minutes. • Ethylene Oxide (EO) with a concentration of 735 mg/L at 55°C (131°F) and 50% to 80% relative humidity for 60 minutes. Aeration time of 8hours at 60°C (140°F).	• Steam sterilization cycle parameters are 30 minutes at 121℃. • EO sterilization cycle is 4 hours at 55℃ with a relative humidity between 50%-85% and a sterilant concentration of 600 mg/L	Different

Configuration/ Dimension	Various Size, Heat Sealing	Various Size, Heat Sealing and Self Sealing	Various Size, Heat Sealing	Same
Performance Testing				
Sterilant Penetration Efficacy	The test meet the requirement of SAL 10^{-6}	The test meet the requirement of SAL 10^{-6}	The test meet the requirement of SAL 10^{-6}	Same
Chemical Indicator (CI) Functionality and Endpoint	The sterilant penetrated through the pouch configuration and affected the CI color change to the endpoint color	The sterilant penetrated through the pouch configuration and affected the CI color change to the endpoint color	The sterilant penetrated through the pouch configuration and affected the CI color change to the endpoint color	Same
Device Design of Steam CI	The color of Chemical Indicator changes from Blue to dark grey, when exposed to Steam	The color of Chemical Indicator changes from Pink to Brown/Black, when exposed to Steam	The color of Chemical Indicator changes from Blue to Greenish Black, when exposed to Steam	Similar
Device Design of EO gas CI	The color of Chemical Indicator changes from Pink to Yellow, when exposed to Steam	The color changes from Blue to Yellow/Brown, when exposed to EO gas	The color changes from - Red to Yellow, when exposed to EO gas	Similar
Thickness Variations (mm) ASTM F 2251	Passed	Passed	Passed	Same
Tensile strength ISO 1924-2	Passed	Passed	Passed	Same
Burst Strength (kPa) ASTM F1140 ;	> 3.0 Kpa Passed	Passed	Passed	Same

ISO 11607-1				
Bubble Leak Test ASTM D 3078 or ASTM-F 2096	No Leakage Passed	Passed	Passed	Same
Seal Peel Test (N/15mm) ASTM F88/F88M ; ISO 11607-1	Min value= 2.08 Passed	Passed	Passed	Same
Dye penetration Test ASTM F1929 ;ISO 11607-1	No Infiltration Passed	Passed	Passed	Same
Microbial Barrier Test DIN 58953-6	CFU = 0 Passed	Passed	Passed	Same
End point stability testing results	The color of chemical indicator for EO sterilization indicator ink is Pink, and the color of chemical indicator for steam sterilization indicator ink is Blue after 5 year shelf life before sterilization.	The color of chemical indicator for EO sterilization indicator ink is Blue, and the color of chemical indicator for steam sterilization indicator ink is Pink after 2 year shelf life before sterilization.	The color of chemical indicator for EO sterilization indicator ink is Red, and the color of chemical indicator for steam sterilization indicator ink is Blue after 2 year shelf life before sterilization.	Similar
	The color of chemical indicator for	The color of chemical indicator for	The color of chemical indicator for	Similar

	EO sterilization indicator ink is Yellow, and the color of chemical indicator for steam sterilization indicator ink is Blue after EO sterilized and 24 months shelf life.	EO sterilization indicator ink is Yellow/Brown , and the color of chemical indicator for steam sterilization indicator ink is Pink after EO sterilized and 6 months shelf life	EO sterilization indicator ink is yellow, and the color of chemical indicator for steam sterilization indicator ink is Blue after EO sterilized and 3 years shelf life	
	The color of chemical indicator for EO sterilization indicator ink is Pink, and the color of chemical indicator for steam sterilization indicator ink is Dark Grey after steam sterilized and 24 months shelf life.	The color of chemical indicator for EO sterilization indicator ink is Bue, and the color of chemical indicator for steam sterilization indicator ink is Brown/Black after steam sterilized and 6 months shelf life.	The color of chemical indicator for EO sterilization indicator ink is Red, and the color of chemical indicator for steam sterilization indicator ink is Greenish Black after steam sterilized and 6 months shelf life.	Similar
Maintenance of Sterility	24 months	6 months	3 years post EO gas sterilization 6 months post Steam sterilization	Different
Shelf Life	5 years from date of manufacture for EO and Steam Indicators	3 years from date of manufacture for EO and Steam Indicators	3 years from date of manufacture for EO and Steam Indicators	Different
Biocompatibility	Conform with ISO10993-1 (ISO10993-4, ISO10993-5, ISO10993-10, ISO10993-11)	Conform with ANSI/AAMI/ISO 10993-10	Conform with ISO 10993 standards	Same

The technological characteristics of the subject device are identical to those of predicate device. The subject device has the same basic design as the predicate device.
The comparison between the subject and predicate devices is based on the following:
• Same intended use
• Same indications for use
• Similar material types that meet ISO 10993 biocompatibility requirements
• Same sterilization methods (EO and Steam sterilization process)
• Same fundamental technology/principal of operation/user interface

The sterilization parameters of the subject device is different with those of the predicate device, but the EO sterilization validation results demonstrate the subject device fully meet the requirements of ISO 11135 and the steam sterilization validation results fully meet the requirements of ISO 17665-1. The subject device is confirmed to be substantial equivalence as the predicate device.

8.0 Summary of Clinical Testing

No clinical study is included in this submission.

9.0 Conclusion

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 K212338.