February 24, 2025

Anqing Clean Dental Instrument Technology Co., Ltd.
% Wang Boyle
General Manager
Shanghai Truthful Information Technology Co., Ltd.
Room 1801, No. 161 East Lujiazui Rd., Pudong
Shanghai, 200120
China

Re: K241565
Trade/Device Name: Sterilization Package/Reel
Regulation Number: 21 CFR 880.6850
Regulation Name: Sterilization Wrap
Regulatory Class: Class II
Product Code: FRG, JOJ
Dated: January 20, 2025
Received: January 24, 2025

Dear Wang Boyle:

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.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

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) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Stephen A. Anisko -S

Digitally signed by Stephen A. Anisko -S
Date: 2025.02.24 20:03:28 -05'00'

for: Christopher K. Dugard, M.S.
Director
DHT4C: Division of Infection Control Devices
OHT4: Office of Surgical and Infection Control 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: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K241565

Device Name
Sterilization Package/Reel

Indications for Use *(Describe)*
The Sterilization Package/Reel is 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 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℃(140℉).

Furthermore, the Sterilization Package/Reel maintains the enclosed devices up until 6 months 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 Sterilization Package/Reel has undergone either a steam or EO sterilization process.

The Sterilization Package/Reel is offered 3 types in the following:
Self -Seal Sterilization Pouch;
Flat Sterilization Reel;
Gusseted Sterilization Reel.

The following table (Table 1) lists the model numbers of the Sterilization Package/Reel by type, model, dimensions, and content/max. load (lbs.):

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.

Table 1. The model numbers of Sterilization Package/Reel (Type, Model and Dimension and Content/Max. Load)

Product Name	Item	Specification Size (WXL)		Content/Max Load(lbs)		
		Inch	Dimension	Metal	Plastic	Gauze/Linens
Self Sealing Sterilization Pouch	KLDT-90165	3.5”x6.5”	90mmx165mm	0.12	0.11	0.1
	KLDT-305430	12”x17”	305mmx430mm	1.10	1.09	0.66
	KLDT-70230	2.75”x9”	70mm×230mm	0.09	0.08	0.07
	KLDT-135280	3⅓″×11”	135mmx280mm	0.50	0.47	0.46
	KLDT-90135	3.5”x5.25”	90mmx135mm	0.10	0.09	0.08
	KLDT-70260	2.75”x10”	70mm×260mm	0.10	0.09	0.08
	KLDT-90260	3.5”x10”	90mmx260mm	0.15	0.14	0.12
	KLDT-135260	3⅓″×10”	135mmx260mm	0.48	0.46	0.45
	KLDT-250370	10”x14.5”	250mmx370mm	1.06	1.05	0.62
	KLDT-190360	7.5”x14”	190mmx360mm	0.60	0.58	0.55
	KLDT-57130	2.25”x5”	57mm×130mm	0.04	0.03	0.005
	KLDT-57100	2.25”x4”	57mm×100mm	0.03	0.02	0.004
	KLDT-135330	3⅓″×13”	135mmx330mm	0.55	0.53	0.50
	KLDT-90230	3.5”x9”	90mmx230mm	0.14	0.13	0.11
Flat Sterilization Reel	KLDT-200200	8″	200mm×200m	0.60	0.58	0.55
	KLDT-300200	12″	300mm×200m	1.04	1.03	0.60
	KLDT-75200	3″	75mm×200m	0.09	0.05	0.004
	KLDT-100200	4″	100mm×200m	0.14	0.13	0.11
	KLDT-50200	2″	50mm×200m	0.02	0.01	0.003
	KLDT-400200	16″	400mm×200m	1.08	1.07	0.64
	KLDT-250200	10″	250mm×200m	0.80	0.78	0.58
	KLDT-350200	14″	350mm×200m	1.06	1.05	0.62
	KLDT-55200	2.25″	55mm×200m	0.03	0.02	0.003
	KLDT-150200	6″	150mm×200m	0.55	0.53	0.50
Gusseted Sterilization Reel	KLDT-75100	3″	75mm×30mm×100m	0.09	0.05	0.004
	KLDT-350100	14″	350mm×80mm×100m	1.06	1.05	0.62
	KLDT-150100	6″	150mm×50mm×100m	0.55	0.53	0.50
	KLDT-400100	16″	400mm×80mm×100m	1.08	1.07	0.64
	KLDT-250100	10″	250mm×65mm×100m	0.80	0.78	0.58
	KLDT-300100	12″	300mm×75mm×100m	1.04	1.03	0.60
	KLDT-200100	8″	200mm×55mm×100m	0.60	0.58	0.55

	KLDT-100100	4″	100mm×50mm×100m	0.14	0.13	0.11

510(k) Summary

K241565

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: Anqing Clean Dental Instrument Technology Co.,LTD.
Address: Floor 2, D4-A,Jiabao Industrial Park.Yangtze River Bridge Economic Development Zone ,246000 Anqing City, Anhui Province,China
Tel: 0086-556-5577869
Contact: Wu Yiming

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: Jan.20,2025

2.0 Device Information

Trade/Device name: Sterilization Package/Reel
Common name: Sterilization Package/Reel
Classification name: Sterilization Wrap;
Classification Product Code: FRG,JOJ
Regulation number: 21 CFR880.6850
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

4.0 Device Description

The medical devices are inserted into the Sterilization Package/Reel,sealed, and then sterilized. After completion of the sterilization process, the Pouch/Roll main- tains the 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 6 months post Steam or EO gas sterilization.
The Self-seal Sterilization Package permits the sealing of the pouch without the need of heat-sealing equipment, while the Heat-Seal Sterilization Reel are heat-sealed prior to processing in the steam/or EO Sterilization.
The chemical indicators ink printed on the "medical dialysis paper" will exhibit a color change after the Package/Reel is exposed to steam or ethylene oxide gas. The color of the Chemical Indicator changes from blue to black when exposed to Steam. And the color changes from pink to yellow, when exposed to EO gas.

The Chemical Indicator which is Type 1 Process Indicator as categorized by ISO 11140-1:2014 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 Chemical Indicators do not signify sterilization; they only indicate that the indicator has been exposed to Steam/or EO gas.

5.0 Indication for Use Statement

The Sterilization Package/Reel is 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 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℃(140℉).

Furthermore, the Sterilization Package/Reel maintains the enclosed devices up until 6 months 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 Sterilization Package/Reel has undergone either a steam or EO sterilization process.

The Sterilization Package/Reel is offered 3 types in the following:
Self -Seal Sterilization Pouch;
Flat Sterilization Reel;
Gusseted Sterilization Reel.

The following table (Table 1) lists the model numbers of the Sterilization Package/Reel by type, model, dimensions, and content/max. load (lbs.):

Table 1. The model numbers of Sterilization Package/Reel (Type, Model and Dimension and Content/Max. Load)

Product Name	Item	Specification Size (WXL)		Content/Max Load(lbs)		
		Inch	Dimension	Metal	Plastic	Gauze/Linens
Self Sealing Sterilization Pouch	KLDT-90165	3.5”x6.5”	90mmx165mm	0.12	0.11	0.1
	KLDT-305430	12”x17”	305mmx430mm	1.10	1.09	0.66
	KLDT-70230	2.75”x9”	70mm×230mm	0.09	0.08	0.07
	KLDT-135280	3⅓″×11”	135mmx280mm	0.50	0.47	0.46
	KLDT-90135	3.5”x5.25”	90mmx135mm	0.10	0.09	0.08
	KLDT-70260	2.75”x10”	70mm×260mm	0.10	0.09	0.08
	KLDT-90260	3.5”x10”	90mmx260mm	0.15	0.14	0.12
	KLDT-135260	3⅓″×10”	135mmx260mm	0.48	0.46	0.45
	KLDT-250370	10”x14.5”	250mmx370mm	1.06	1.05	0.62
	KLDT-190360	7.5”x14”	190mmx360mm	0.60	0.58	0.55
	KLDT-57130	2.25”x5”	57mm×130mm	0.04	0.03	0.005
	KLDT-57100	2.25”x4”	57mm×100mm	0.03	0.02	0.004
	KLDT-135330	3⅓″×13”	135mmx330mm	0.55	0.53	0.50
	KLDT-90230	3.5”x9”	90mmx230mm	0.14	0.13	0.11
Flat Sterilization Reel	KLDT-200200	8″	200mm×200m	0.60	0.58	0.55
	KLDT-300200	12″	300mm×200m	1.04	1.03	0.60
	KLDT-75200	3″	75mm×200m	0.09	0.05	0.004
	KLDT-100200	4″	100mm×200m	0.14	0.13	0.11
	KLDT-50200	2″	50mm×200m	0.02	0.01	0.003
	KLDT-400200	16″	400mm×200m	1.08	1.07	0.64
	KLDT-250200	10″	250mm×200m	0.80	0.78	0.58
	KLDT-350200	14″	350mm×200m	1.06	1.05	0.62
	KLDT-55200	2.25″	55mm×200m	0.03	0.02	0.003
	KLDT-150200	6″	150mm×200m	0.55	0.53	0.50
Gusseted Sterilization Reel	KLDT-75100	3″	75mm×30mm×100m	0.09	0.05	0.004
	KLDT-350100	14″	350mm×80mm×100m	1.06	1.05	0.62
	KLDT-150100	6″	150mm×50mm×100m	0.55	0.53	0.50
	KLDT-400100	16″	400mm×80mm×100m	1.08	1.07	0.64
	KLDT-250100	10″	250mm×65mm×100m	0.80	0.78	0.58
	KLDT-300100	12″	300mm×75mm×100m	1.04	1.03	0.60
	KLDT-200100	8″	200mm×55mm×100m	0.60	0.58	0.55

	KLDT-100100	4″	100mm×50mm×100m	0.14	0.13	0.11

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 2: Performance testing summary – Bench

Test Item	Test Methodology	Acceptance Criteria or End Point	Test Results
Sterilization Process Validation	ISO 11135:2014	Ethylene oxide: 60 minutes at 55 ℃; relative humidity between 50%- 80%; ethylene oxide concentration is 735 mg/L, 8 hours aeration time at 60℃(140℉). SAL=10^{-6}	SAL=10^{-6} Pass
	ISO 17665-1:2006; ISO TS 17665-2:2009	Steam; 4 minutes at 132℃; 30 minutes dry time. SAL=10^{-6}	SAL=10^{-6} Pass
EO/ECH Residuals	ISO 10993-7:2008	EO < 4mg/d ECH < 9mg/d	Pass
Package Integrity / Material Compatibility /Sterility Maintenance	ASTM F 2251-13	52μm±10%	Pass
	ASTM F1140/F1140M-13	Burst value > 3.2 Kpa or No Burst	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-21	Seal strength > 2.5 (N/15mm)	Pass
	ISO 1924-2:2008	Tensile strength: CD≧2.2KN/m,MD≧4.4KN/m	Pass
	ASTM F2096-11	No Leakage	No Leakage Pass
	DIN 58953-6	CFU = 0	CFU = 0 Pass
	ISO 5636-3	10–50 mL/min·m²	20–30 mL/min·m² Pass

Chemical Indicator Efficacy Testing	ISO 11140-1:2014 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.	Steam: The color of CI changes from blue to black, when exposed to Steam; EO: The color of CI changes from pink to yellow, when exposed to EO gas.	The real time aging test was carried out that demonstrates: the test device which exposed to Steam maintain the color of black, the test group which exposed to EO maintain the color of yellow, and the real time aging test was carried out on the empty Sterilization Package/Reel that demonstrates the test device maintain the original color within the stated validity period of 2 years.
Shelf-Life Validation	/	Shelf Life:2 Years; Shelf Life after Sterilized: 6 months	Pass

Biocompatibility Testing

The biocompatibility evaluation for the Sterilization Package/Reel was conducted in accordance with the FDA's Biocompatibility Guidance "Use of International Standard ISO 10993-1, 'Biological Evaluation of Medical Devices - Part 1: Evaluation and Testing Within a Risk Management Process'"

Table 3 Summary test of Biocompatibility Testing

Biocompatibility testing	ISO 10993-5:2009	Non-cytotoxic	Under conditions of the study, did not show potential toxicity to L-929 cells. Pass
	ISO 10993-23:2021	Non-irritating	Under the conditions of the study, not an irritant. Pass
	ISO 10993-10:2021	Non-sensitizing	Under conditions of the study, not a sensitizer. Pass

7.0 Technological Characteristic Comparison Table

Table 4- Comparison of Technology Characteristics

Item	Subject Device K241565	Predicate Device K212338	Comparison Analysis
Product Name	Sterilization Package/Reel	SterileRight sterilization pouch and roll	----
Product Code	FRG,JOJ	FRG,JOJ	Same
Regulation No.	21 CFR 880.6850	21 CFR 880.6850 21 CFR 880.2800	Same
Class	II	II	Same
Indication for Use	The Sterilization Package/Reel is 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 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℃ (140℉). Furthermore, the Sterilization Package/Reel maintains the enclosed devices up until 6 months 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 Sterilization Package/Reel has undergone either a steam or EO sterilization process.	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. • 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	Similar

	The Sterilization Package/Reel is offered 3 types in the following: Self -Seal Sterilization Pouch; Flat Sterilization Reel; Gusseted Sterilization Reel.	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. 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 dialysis paper and transparent colored PET/CPP composite film , EO and Steam Process Indicator, Print Ink, adhesive	Medical Grade Paper, CPP, PET, adhesive,EO and Steam Process Indicator, Print Ink. Tyvek® , PET, PE, adhesive.	Similar
Sterilization Cycles	• Steam Sterilization at 132°C (270°F) for 4 minutes; Drying time of 30 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℃ (140℉).	•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).	Similar
Configuration/ Dimension	Various Size, Heat Sealing and Self Sealing	Various Size, Heat Sealing and Self Sealing	Same
Sterilant Penetration Efficacy	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	Same
Device Design of Steam CI	The color of Chemical Indicator changes from Blue to	The color of Chemical Indicator changes from Pink to	Similar

	Black, when exposed to Steam	Brown/Black, when exposed to Steam	
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	Similar
Thickness Variations (mm) ASTM F 2251	Passed	Passed	Same
Tensile strength ISO 1924-2	Passed	Passed	Same
Burst Strength (kPa) ASTM F1140	Passed	Passed	Same
Bubble Leak Test ASTM D 3078 or ASTM-F 2096	Passed	Passed	Same
Seal Peel Test (N/15mm) ASTM F88/F88M ; ISO 11607-1	Passed	Passed	Same
Dye penetration Test ASTM F1929	Passed	Passed	Same
Microbial Barrier Test DIN 58953-6	Passed	Passed	Same
Air permeance testing ISO 5636-3	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 2 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.	Similar
	The color of chemical indicator for EO sterilization indicator ink is Yellow, and the color of chemical indicator for steam sterilization	The color of chemical indicator for EO sterilization indicator ink is Yellow/Brown , and the color of chemical indicator for steam	Similar

	indicator ink is Blue after EO sterilized and 6 months shelf life.	sterilization indicator ink is Pink after EO sterilized and 6 months 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 Black after steam sterilized and 6 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.	Similar
Maintenance of Sterility	6 months	6 months	Same
Shelf Life	2 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 (ISO10993-5, ISO10993-10)	Conform with ANSI/AAMI/ISO 10993-10	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 are little 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.

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.