October 10, 2019

MDK (ShangHai) Medical Packing Co., Ltd.
Ray Wang
Official Correspondent
No. 233 Fengijan Rd, FengCheng Town, FengXian District
ShangHai, 201409 Cn

Re: K182184
Trade/Device Name: Paper Sterilization Pouch and Roll (Sterilization Pouch Flat, Sterilization Pouch Gusseted, Sterilization Roll Flat and Sterilization Roll Gusseted)
Regulation Number: 21 CFR 880.6850
Regulation Name: Sterilization Wrap
Regulatory Class: Class II
Product Code: FRG, JOJ
Dated: September 5, 2019
Received: September 9, 2019

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,

For Elizabeth Claverie, M.S.
Assistant Director for THT4B2
Acting Assistant Director for THT4B1
DHT4B: Division of Infection Control
and Plastic Surgery Devices
OHT4: Office of Surgical
and Infection Control Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K182184

Device Name
Paper Sterilization Pouch and Roll (Sterilization Pouch Flat, Sterilization Pouch Gusseted, Sterilization Roll Flat and Sterilization Roll Gusseted)

Indications for Use *(Describe)*

Sterilization Pouch Flat

The Sterilization Pouch Flat are intended to be used to enclose another medical devices that is to be sterilized by a health care provider. It is intended to allow sterilization of the enclosed medical device and also to maintain sterility of the enclosed device until used.

The Sterilization Pouch Flat are intended for sterilization of dental instruments, excluding complex devices (endoscopes and instruments with lumen/channels).

The intended sterilization cycles are listed below:

Gravity Steam; 30 minutes at 121 ℃; 25 minutes dry time.

Ethylene oxide: 4 hours at 55 ℃; relative humidity between 50%- 85%; ethylene oxide concentration is 600 mg/L, 8 hours aeration time at 60℃.

The pouch's external chemical ink indicators are designed to indicate to the user that the pouch has undergone either a steam or EtO sterilization process.

The Sterilization Pouch Flat are not intended use for any load with lumen/channels and complex device. The maximum wrapped package weight for each pouch is 1470 g.

The sterilization pouch maintains the enclosed devices up until 6 months post sterilization.

Sterilization Pouch Gusseted

The Sterilization Pouch Gusseted are intended to be used to enclose another medical devices that is to be sterilized by a health care provider. It is intended to allow sterilization of the enclosed medical device and also to maintain sterility of the enclosed device until used.

The Sterilization Pouch Gusseted are intended for sterilization of dental instruments, excluding complex devices (endoscopes and instruments with lumen/channels).

The intended sterilization cycles are listed below:

Gravity Steam; 30 minutes at 121 ℃; 25 minutes dry time.

Ethylene oxide: 4 hours at 55 ℃; relative humidity between 50%- 85%; ethylene oxide concentration is 600 mg/L, 8 hours aeration time at 60℃.

The pouch's external chemical ink indicators are designed to indicate to the user that the pouch has undergone either a steam or EtO sterilization process.

The Sterilization Pouch Gusseted are not intended use for any load with lumen/channels and complex device. The maximum wrapped package weight for each pouch is 1470g.

The sterilization pouch maintains the enclosed devices up until 6 months post sterilization.

Sterilization Roll Flat

The Sterilization Roll Flat are intended to be used to enclose another medical devices that is to be sterilized by a health care provider. It is intended to allow sterilization of the enclosed medical device and also to maintain sterility of the enclosed device until used.

The Sterilization Roll Flat are intended for sterilization of dental instruments, excluding complex devices (endoscopes and instruments with lumen/channels).

The intended sterilization cycles are listed below:

Gravity Steam; 30 minutes at 121 ℃; 25 minutes dry time.

Ethylene oxide: 4 hours at 55 ℃; relative humidity between 50%- 85%; ethylene oxide concentration is 600 mg/L, 8 hours aeration time at 60℃.

The pouch's external chemical ink indicators are designed to indicate to the user that the pouch has undergone either a steam or EtO sterilization process.
The Sterilization Roll Flat are not intended use for any load with lumen/channels and complex device. The maximum wrapped package weight for each pouch is 910g.
The sterilization roll maintains the enclosed devices up until 6 months post sterilization.

Sterilization Roll Gusseted
The Sterilization Roll Gusseted are intended to be used to enclose another medical devices that is to be sterilized by a health care provider. It is intended to allow sterilization of the enclosed medical device and also to maintain sterility of the enclosed device until used.
The Sterilization Roll Gusseted are intended for sterilization of dental instruments, excluding complex devices (endoscopes and instruments with lumen/channels).
The intended sterilization cycles are listed below:
Gravity Steam; 30 minutes at 121 ℃; 25 minutes dry time.
Ethylene oxide: 4 hours at 55 ℃; relative humidity between 50%- 85%; ethylene oxide concentration is 600 mg/L, 8 hours aeration time at 60℃.
The pouch's external chemical ink indicators are designed to indicate to the user that the pouch has undergone either a steam or EtO sterilization process.
The Sterilization Roll Gusseted are not intended use for any load with lumen/channels and complex device. The maximum wrapped package weight for each pouch is 910g.
The sterilization roll maintains the enclosed devices up until 6 months post 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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510(k) Summary

This 510(k) Summary of 510(k) is being submitted in accordance with Title 21, CFR Section 807.92.

The assigned 510(k) Number: K182184

1. Date of Preparation: 10/7/2018

2. Sponsor Identification

MDK（ShangHai）Medical Packing Co., Ltd.
No.:233 Fengjian Rd, FengCheng Town, FengXian District, Shanghai, 201409, China

Establishment Registration Number: Not yet registered or the Number not issued yet.

Contact Person: Gong Yaoren
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3. Designated Submission Correspondent

Mr. Ray Wang
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Fax: +86-10-56335780
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4. Identification of Proposed Device

Trade Name: Paper Sterilization Pouch and Roll(Sterilization Pouch Flat, Sterilization Pouch Gusseted, Sterilization Roll Flat and Sterilization Roll Gusseted)

Common Name: Sterilization Pouches

Type(s): Sterilization Pouch Flat/ Sterilization Pouch Gusseted/ Sterilization Roll Flat/ Sterilization Roll Gusseted

Regulatory Information

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

Classification: 2

Product Code: FRG/JOJ

Regulation Number: 21 CFR 880.6850/ 21 CFR 880.2800

Review Panel: General Hospital

5. Identification of Predicate Device(s)

Predicate Device
510(k) Number: K143637
Product Name: U & U Sterilization Pouch and Roll
Model Name: U&U Medical Technology Co., Ltd.

6. Device Description

The Paper Sterilization Pouch and Roll 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; 30 minutes at 121ºC; 25 minutes dry time.
Ethylene oxide: 4 hours at 55 ºC; relative humidity between 50%- 85%; ethylene oxide concentration is 600 mg/L, 8 hours aeration time at 60 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 6 months post sterilization.

The Pouch/Roll is printed with a chemical indicator bar that changes from Red/Pink to Yellow/Brown (EtO) or Blue to Brown/Black (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.

The Paper Sterilization Pouch and Roll is offered in the follow 4 types:
* Sterilization Pouch Flat;
* Sterilization Pouch Gusseted;
* Sterilization Pouch Roll Flat;
* Sterilization Pouch Roll Gusseted.

The defining characteristics of the 4 types as follows:

Sterilization Pouch Flat: These pouches are made from a medical grade paper and plastic (CPP/PET) film that is heat sealed on three sides, the forth side is left opened and will be heat-sealed when using. The Process Indicators Ink printed on the Pouch will exhibit a color change after the pouch is exposed to EtO gas or Steam.

Sterilization Pouch Gusseted: These rolls are the same as the Sterilization Pouch Flat, with the Heat Sealing except that the plastic film is folded on both longest sides instead of flat. This design is convenient to enclose the medical devices with certain height.

Sterilization Roll Flat: These rolls are made from a medical grade paper and plastic (CPP/PET) film that are heat sealed on opposite two sides. It will be cut into the suitable length and the opened sides will be heat-sealed. The indicators printed on it are the same as the sterilization pouches.

Sterilization Roll Gusseted: These rolls are the same with the flat sterilization roll, except that the plastic film is folded on both longest sides instead of flat. This design is convenient to enclose the medical devices with certain height.

Type	Model	Dimension in S.I
Sterilization Pouch Flat	PFP001	55mm*150mm
	PFP002	55mm*200mm
	PFP003	55mm*250mm
	PFP004	55mm*300mm
	PFP005	75mm*150mm
	PFP006	75mm*200mm
	PFP007	75mm*250mm
	PFP008	75mm*300mm
	PFP009	100mm*150mm
	PFP010	100mm*200mm
	PFP011	100mm*250mm
	PFP012	100mm*300mm
	PFP013	100mm*350mm
	PFP014	100mm*400mm
	PFP015	125mm*150mm
	PFP016	125mm*200mm
	PFP017	125mm*250mm
	PFP018	125mm*300mm
	PFP019	125mm*350mm
	PFP020	125mm*400mm
	PFP021	150mm*200mm
	PFP022	150mm*250mm
	PFP023	150mm*300mm
	PFP024	150mm*350mm
	PFP025	150mm*400mm
	PFP026	200mm*250mm
	PFP027	200mm*300mm
	PFP028	200mm*350mm
	PFP029	200mm*400mm
	PFP030	200mm*450mm

	PFP031	250mm*300mm
	PFP032	250mm*350mm
	PFP033	250mm*400mm
	PFP034	250mm*450mm
	PFP035	300mm*300mm

Type	Model	Dimension in S.I
	PFP036	300mm*350mm
	PFP037	300mm*400mm
	PFP038	300mm*450mm
	PFP039	350mm*450mm
	PFP040	450mm*550mm
Sterilization Pouch Gusseted	PGP001	75mm*25mm*150mm
	PGP002	100mm*50mm*300mm
	PGP003	150mm*50mm *350mm
	PGP004	150mm *50mm *450mm
	PGP005	200mm*50mm *350mm
	PGP006	200mm*50mm *450mm
	PGP007	250mm*55mm*400mm
	PGP008	300mm*60mm *400mm
	PGP009	350mm*65mm*450mm
	PGP010	400mm*75mm*500mm
Sterilization Roll Flat	PFR001	55mm *200m
	PFR002	75mm *200m
	PFR003	100mm *200m
	PFR004	125mm *200m
	PFR005	150mm *200m
	PFR006	175mm *200m
	PFR007	200mm *200m
	PFR008	250mm*200m
	PFR009	300mm *200m
	PFR010	350mm *200m
	PFR011	400mm*200m
	PFR012	450mm *200m
Sterilization Roll Gusseted	PGR001	75mm*25mm*100m
	PGR002	100mm*50mm*100m
	PGR003	150mm*50mm*100m
	PGR004	200mm*50mm*100m
	PGR005	250mm*55mm*100m
	PGR006	300mm*60mm*100m
	PGR007	350mm*65mm*100m
	PGR008	400mm*75mm*100m

7. Indication Use Statement:

Sterilization Pouch Flat

The Sterilization Pouch Flat are intended to be used to enclose another medical devices that is to be sterilized by a health care provider. It is intended to allow sterilization of the enclosed medical device and also to maintain sterility of the enclosed device until used. The Sterilization Pouch Flat are intended for sterilization of dental instruments, excluding complex devices (endoscopes and instruments with lumen/channels). The intended sterilization cycles are listed below:

Steam; 30 minutes at 121 ºC; 25 minutes dry time.
Ethylene oxide: 4 hours at 55 ºC; relative humidity between 50%- 85%; ethylene oxide concentration is 600 mg/L, 8 hours aeration time at 60 ºC.

The pouch's external chemical ink indicators are designed to indicate to the user that the pouch has undergone either a steam or EtO sterilization process. The Sterilization Pouch Flat are not intended use for any load with lumen/channels and complex device. The maximum wrapped package weight for each pouch is 1470 g. The sterilization pouch maintains the enclosed devices up until 6 months post sterilization.

Sterilization Pouch Gusseted

The Sterilization Pouch Gusseted are intended to be used to enclose another medical devices that is to be sterilized by a health care provider. It is intended to allow sterilization of the enclosed medical device and also to maintain sterility of the enclosed device until used. The Sterilization Pouch Gusseted are intended for sterilization of dental instruments, excluding complex devices (endoscopes and instruments with lumen/channels). The intended sterilization cycles are listed below:

Steam; 30 minutes at 121 ºC; 25 minutes dry time.
Ethylene oxide: 4 hours at 55 ℃; relative humidity between 50%- 85%; ethylene oxide concentration is 600 mg/L, 8 hours aeration time at 60 ºC.

The pouch's external chemical ink indicators are designed to indicate to the user that the pouch has undergone either a steam or EtO sterilization process. The Sterilization Pouch Gusseted are not intended use for any load with lumen/channels and complex device. The maximum wrapped package weight for each pouch is 1470g. The sterilization pouch maintains the enclosed devices up until 6 months post sterilization.

Sterilization Roll Flat

The Sterilization Roll Flat are intended to be used to enclose another medical devices that is to be sterilized by a health care provider. It is intended to allow sterilization of the enclosed medical device and also to maintain sterility of the enclosed device until used.
The Sterilization Roll Flat are intended for sterilization of dental instruments, excluding complexdevices (endoscopes and instruments with lumen/channels). The intended sterilization cycles are listed below:

Steam; 30 minutes at 121 ºC; 25 minutes dry time.
Ethylene oxide: 4 hours at 55 ºC; relative humidity between 50%- 85%; ethylene oxide concentration is 600 mg/L, 8 hours aeration time at 60 ºC.

The pouch's external chemical ink indicators are designed to indicate to the user that the pouch has undergone

either a steam or EtO sterilization process. The Sterilization Roll Flat are not intended use for any load with lumen/channels and complex device. The maximum wrapped package weight for each pouch is 910g. The sterilization roll maintains the enclosed devices up until 6 months post sterilization.

Sterilization Roll Gusseted

The Sterilization Roll Gusseted are intended to be used to enclose another medical devices that is to be sterilized by a health care provider. It is intended to allow sterilization of the enclosed medical device and also to maintain sterility of the enclosed device until used. The Sterilization Roll Gusseted are intended for sterilization of dental instruments, excluding complex devices (endoscopes and instruments with lumen/channels). The intended sterilization cycles are listed below:

Steam; 30 minutes at 121 ºC; 25 minutes dry time.
Ethylene oxide: 4 hours at 55 ºC; relative humidity between 50%- 85%; ethylene oxide concentration is 600 mg/L, 8 hours aeration time at 60 ºC.

The pouch's external chemical ink indicators are designed to indicate to the user that the pouch has undergone either a steam or EtO sterilization process. The Sterilization Roll Gusseted are not intended use for any load with lumen/channels and complex device. The maximum wrapped package weight for each pouch is 910g. The sterilization roll maintains the enclosed devices up until 6 months post sterilization.

8. Technological Characteristics Comparison Table

Table 1 General Comparison

ITEM	Proposed Device	Predicate Device K143637	Remark
Indication For Use	**Sterilization Pouch Flat** The ***Sterilization Pouch Flat*** are intended to be used to enclose another medical devices that is to be sterilized by a health care provider. It is intended to allow sterilization of the enclosed medical device and also to maintain sterility of the enclosed device until used. The ***Sterilization Pouch Flat*** are intended for sterilization of dental instruments, excluding complex devices (endoscopes and instruments with lumen/channels). The intended sterilization cycles are listed below: Steam; 30 minutes at 121 ℃; 25 minutes dry time. Ethylene oxide: 4 hours at 55 ℃; relative humidity between 50%- 85%; ethylene oxide concentration is 600 mg/L, 8 hours aeration time at 60℃. The pouch's external chemical ink indicators are designed to indicate to the user that the pouch has undergone either a steam or EtO sterilization process. The ***Sterilization Pouch Flat*** are not intended use for any load with lumen/channels and complex device. The maximum wrapped package weight for each pouch is 1470 g. The sterilization pouch maintains the enclosed devices up until 6 months post sterilization.	The U&U sterilization pouch and roll are intended to provide health care workers with an effective method to enclose devices intended for sterilization in steam and Ethylene Oxide (EtO). The recommended gravity steam sterilization cycle parameters are 30 minutes at 121 ℃. The recommended EtO sterilization cycle is 4 hours at 55 ℃ with a relative humidity between 50%- 85% and a sterilant concentration of 600 mg/L. Furthermore, the sterilization pouch and roll maintain the enclosed devices up until 90Days post 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 EtO sterilization process. The recommended gravity steam sterilization cycle parameters Steam sterilization temperature: 121°C (250°F) Steam sterilization time: 30 minutes. Drying time: 25 minutes The recommended EtO sterilization cycle parameters EtO sterilization temperature: 55°C (130 °F) EtO sterilization time: 4 hours EtO sterilization humidity: 50% to 85% RH EtO sterilization concentration:600mg/L	Similar
	Sterilization Pouch Gusseted The ***Sterilization Pouch Gusseted*** are intended to be used to enclose another medical devices that is to be sterilized by a health care provider. It is intended to		

	allow sterilization of the enclosed medical device and also to maintain sterility of the enclosed device until used. The ***Sterilization Pouch Gusseted*** are intended for sterilization of dental instruments, excluding complex devices (endoscopes and instruments with lumen/channels). The intended sterilization cycles are listed below: Steam; 30 minutes at 121 ℃; 25 minutes dry time. Ethylene oxide: 4 hours at 55 ℃; relative humidity between 50%- 85%; ethylene oxide concentration is 600 mg/L, 8 hours aeration time at 60℃. The pouch's external chemical ink indicators are designed to indicate to the user that the pouch has undergone either a steam or EtO sterilization process. The ***Sterilization Pouch Gusseted*** are not intended use for any load with lumen/channels and complex device. The maximum wrapped package weight for each pouch is 1470g. The sterilization pouch maintains the enclosed devices up until 6 months post sterilization.	Aeration time: 8 hours. Aeration Temperature: 60°C Sterilization load claim: Two types of sterilization loads were validated. Load A: Metal medical instruments and Hand-control pen, the total weight is 24lbs. Load B: Tubing (Silicone) and Surgical Towels. The total weight is 18lbs.	
	Sterilization Roll Flat The ***Sterilization Roll Flat*** are intended to be used to enclose another medical devices that is to be sterilized by a health care provider. It is intended to allow sterilization of the enclosed medical device and also to maintain sterility of the enclosed device until used. The ***Sterilization Roll Flat*** are intended for sterilization of dental instruments, excluding complex devices (endoscopes and instruments with lumen/channels). The intended sterilization cycles are listed below: Steam; 30 minutes at 121 ℃; 25 minutes dry time. Ethylene oxide: 4 hours at 55 ℃; relative humidity between 50%- 85%; ethylene		

	oxide concentration is 600 mg/L, 8 hours aeration time at 60℃. The pouch's external chemical ink indicators are designed to indicate to the user that the pouch has undergone either a steam or EtO sterilization process. The ***Sterilization Roll Flat*** are not intended use for any load with lumen/channels and complex device. The maximum wrapped package weight for each pouch is 910g. The sterilization roll maintains the enclosed devices up until 6 months post sterilization.		
	Sterilization Roll Gusseted The ***Sterilization Roll Gusseted*** are intended to be used to enclose another medical devices that is to be sterilized by a health care provider. It is intended to allow sterilization of the enclosed medical device and also to maintain sterility of the enclosed device until used. The ***Sterilization Roll Gusseted*** are intended for sterilization of dental instruments, excluding complex devices (endoscopes and instruments with lumen/channels). The intended sterilization cycles are listed below: Steam; 30 minutes at 121 ℃; 25 minutes dry time. Ethylene oxide: 4 hours at 55 ℃; relative humidity between 50%- 85%; ethylene oxide concentration is 600 mg/L, 8 hours aeration time at 60℃. The pouch's external chemical ink indicators are designed to indicate to the user that the pouch has undergone either a steam or EtO sterilization process. The ***Sterilization Roll Gusseted*** are not intended use for any load with lumen/channels and complex device. The maximum wrapped package weight for each pouch is 910g. The sterilization roll maintains the enclosed devices up until 6 months post sterilization.		

Material Composition	Top Web - Medical Porous Paper Bottom Web - Medical Plastic film(CPP) EtO gas indicator ink-Process Indicators Steam indicator ink-Process Indicators	Top Web - Medical Porous Paper Bottom Web - Medical Plastic film(CPP) EtO gas indicator ink-Process Indicators class 1 Steam indicator ink-Process Indicators class 1	Similar
Sterilization Cycles	Prevacuum steam; 30 minutes at 121 ℃; 25 minutes dry time. Ethylene oxide: 4 hours at 55 ℃; relative humidity between 50%- 85% and a sterilant concentration of 600 mg/L.	The recommended gravity steam sterilization cycle parameters are 30 minutes at 121 ℃. The recommended EtO sterilization cycle is 4 hours at 55 ℃ with a relative humidity between 50%-85% and a sterilant concentration of 600 mg/L.	Similar
Configuration/ Dimension	Various Size, Heat Sealing	Various Size, Heat Sealing and Self Sealing	Similar
Air Permeance	The maximum equivalent pore size diameter shall not exceed 50um.	The maximum equivalent pore size diameter shall not exceed 50um.	Similar
Microbial Barrier Properties (Packaging Integrity)	Use ASTM 1608 method, the LRV is more than 4.0 Use ASTM 1929 method, the inspection result is PASS	Use ASTM 1608 method, the LRV is more than 3.5 Use ASTM 1929 method, the inspection result is PASS	Similar
Material Compatibility	After sterilization, the materials were not degraded	After sterilization, the materials were not degraded	Similar
Biocompatibility	ISO10993-10, Test for Irritation; ISO10993-10, Test for Skin sensitization; Both were non-cytotoxic post sterilization.	ISO10993-10, Test for Irritation; ISO10993-10, Test for Skin sensitization; Both were non-cytotoxic post sterilization.	Similar
Maintenance of Sterility	6 months	90 Days	Similar
Shelf Life	2 years from date of manufacture for EO and Steam Indicators	18 months from date of manufacture for EO and steam Indicators	Similar
Drying Time	25 minutes	25 minutes	Similar
Aeration Time	8 hours at 60°C	8 hours at 60°C	Similar
Chemical Indicator Efficacy	Changed color EtO- Red/Pink to Yellow/Brown; Steam- Blue to Brown/Black	Changed color EtO- YELLOW to COCOA; Steam- GREEN to PURPLE	Similar
End point stability testing results	The color of chemical indicator for EO sterilization indicator ink is Red/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 could maintain stability as claimed shelf life (18 months from date of manufacture for EO and steam indicators, 90 days maintenance of sterility after sterilization process)	Similar

	The color of chemical indicator for EO sterilization indicator ink is Golden Yellow/Brown, and the color of chemical indicator for steam sterilization indicator ink is Blue after EO sterilized and 6 months shelf life.		
	The color of chemical indicator for EO sterilization indicator ink is Red/Pink , and the color of chemical indicator for steam sterilization indicator ink is Brown/Black after steam sterilized and 6 months shelf life.		

9. Summary of Non-Clinical Testing

The proposed device Non-clinical tests were conducted to subject device. The test results demonstrated that the subject device met the acceptance criteria, and the conducted tests listed as below:

Testing Name	Brief Description of Test	Acceptance criteria OR End Point	Test Results
Tensile strength	ASTM D882-12 Standard Test Methods for Tensile Properties of Thin Plastic Sheeting;	≥4.4 KN/m	The test results of all samples are ≥4.4 KN/m. Pass
Thickness	ASTM F2251-03 Standard Test Method for thickness measurement of flexible packaging material;	138±13 μm	The test results of all samples are in the range of 138±13 μm. Pass
Tear Strength	ASTM D1922-03 Standard Test Method for Propagation tear resistance of plastic film and thin sheeting by pendulum method;	≥ 550 mN/15mm	The test results of all samples are ≥ 550 mN/15mm. Pass
Air permeability coefficient	ISO 5636-3:2013 Paper and board – Determination of air permeance (medium range) – Part 3: Bendtsen method;	≥3.4μm/Pa.s	The test results of all samples are ≥3.4μm/Pa.s. Pass
Burst Strength	ASTM F1140/f1140M-13 Standard Test Methods for internal pressurization failure resistance of unrestrained package;	≥2.0 kPa	The test results of all samples are ≥2.0 kPa. Pass
Microorganism Penetration	ASTM F1608-00 Standard test methods for Microbial Ranking of Porous packaging materials;	Microbial Barrier LRV ≥ 2.0 Retention Rate (spore%) ≥ 99.0%	The Microbial Barrier LRV test results of all samples are ≥2.0.

			The Retention Rate test results of all samples are ≥99.0%. Pass
Chemical Indicator Performance	ISO 11140-1:2009 Sterilization of Health Care Products – Chemical Indicators – Part 1: General Requirements;	Color changed from Red/Pink to Golden Yellow/Brown for EO sterilization indicator ink at the condition of 4 hours at 55 ℃; relative humidity between 50%- 85%; ethylene oxide concentration is 600 mg/L;	Color changed from Red/Pink to Golden Yellow/Brown under indicated condition and no changed under other condition. Pass
		Color changed from Blue to Brown/Black at the condition of Gravity Steam, 121℃, 30 mins;	Color changed from Blue to Brown/Black under indicated condition and no changed under other condition. Pass
Dye penetration	ASTM F1929-12 Standard test methods for detecting seal leaks in porous medical packaging by dye penetration.	No dye leakage	No dye leakage/Pass
Seal strength	ASTM F88-15 Standard Test Method for Seal Strength of Flexible Barrier Materials	≥1.5 N/15 mm	The test results of all samples are ≥1.5 N/15 mm. Pass
EO residue	ISO 10993-7:2008 Biological evaluation of medical devices - Part 7: Ethylene oxide sterilization residuals	No more than 4 mg per set	The test results of all samples are no more than 4 mg per set. Pass
ECH residue		No more than 9 mg per set	The test results of all samples are no more than 9 mg per set. Pass

In Vitro Cytotoxicity	ISO 10993-5:2009 Biological Evaluation of Medical Devices – Part 5: Tests for In Vitro Cytotoxicity;	In Vitro Cytotoxicity	Under the conditions of the study, the test article (pouches and chemical indicator) extract did not show potential toxicity to L-929 cells before and after sterilized.
Skin Irritation AND Skin Sensitization	ISO 10993-10:2010 Biological Evaluation of Medical Devices – Part 10: Tests for irritation and skin sensitization;	Skin sensitization;	Under the conditions of the study, the test article (pouches and chemical indicator) extract did not show no significant evidence of causing skin sensitization in the guinea pig before and after sterilized.
		Skin Irritation	Under the conditions of the study, the test article (pouches and chemical indicator) extract did not induce intracutaneous reactivity in rabbit 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: 6 Months; The performance shall be meet the requirements of : Tensile strength: ≥4.4 KN/m; Thickness: 138±13 μm; Tear Strength: ≥ 550 mN/15mm; Air permeability coefficient: ≥3.4μm/Pa.s; Burst Strength: ≥2.0 kPa;	The test results of all samples are meet the requirements. Pass

		Microbial Barrier LRV ≥ 2.0; Retention Rate (spore%) ≥ 99.0%; Dye penetration: No dye leakage; Seal strength: ≥1.5 N/15 mm; Color of indicator shall be meet the specification.	
Sterilization Process Validation	EO Sterilization Process Validation Test. Conducted the EO sterilization process validation as the method/principle of ISO 14937:2009. Use the half cycle method to validate the EO sterilization cycle claimed in indication for use is effective.	Ethylene oxide: 4 hours at 55 ℃; relative humidity between 50%- 85%; ethylene oxide concentration is 600 mg/L, 8 hours aeration time at 60℃. SAL=10^{-6}.	SAL=10^{-6}. Pass
	Steam Sterilization Process Validation Test. Conducted the Steam sterilization process validation as the method/principle of ISO 14937:2009. Use the half cycle method to validate the EO sterilization cycle claimed in indication for use is effective.	Steam; 30 minutes at 121 ℃; 25 minutes dry time. SAL=10^{-6}.	SAL=10^{-6}. Pass

10. Clinical Test Conclusion

No clinical study is included in this submission.

11. Conclusion

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