July 9, 2019

Tianchang Jiarui Packaging Material Co., Ltd.
% Ray Wang
General Manager
Beijing Believe-Med Technology Service Co., Ltd.
Rm.912, Building #15, XiYueHui, No.5, YiHe North Rd.,
FangShan District
Beijing, 102401 Cn

Re: K181957
Trade/Device Name: Heat Sealing Sterilization Pouch Flat, Heat Sealing Sterilization Pouch Gusseted, Heat Sealing Sterilization Pouch Roll Flat, Heat Sealing Sterilization Pouch Roll Gusseted
Regulation Number: 21 CFR 880.6850
Regulation Name: Sterilization Wrap
Regulatory Class: Class II
Product Code: FRG, JOJ
Dated: June 10, 2019
Received: June 13, 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)*
K181957

Device Name
Heat Sealing Sterilization Pouch Flat, Heat Sealing Sterilization Pouch Gusseted, Heat Sealing Sterilization Pouch Roll Flat, Heat Sealing Sterilization Pouch Roll Gusseted

Indications for Use *(Describe)*
The Heat Sealing 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 Heat Sealing 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:

Prevacuum steam; 4 minutes at 132 ℃; 10 minute dry time.
Ethylene oxide: 1 hours at 55 ℃; relative humidity between 40%- 80%; 100% ethylene oxide at a concentration of 740 mg/L, 7 day aeration time at 20℃.

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 Heat Sealing Sterilization Pouch Flat are not intended use for any load with lumen/channels and complex device. The maximum wrapped package weight for 500 x 600 mm size pouch is 1470 g, 200 x 300 mm size pouch is 300g, 90 x 559 mm size pouch is 250g, and 102 x 203 size pouch is 110g.

The sterilization pouch maintains the sterility of the enclosed devices for up to 6 months post sterilization.

Device Size (mm): 90x559, 102x203, 127x381, 130x360, 150x200, 150x300, 152x254, 152x559, 191x330, 200x300, 203x406, 300x400, 305x381, 305x457, 400x500, 457x559, 500x600.

Heat Sealing Sterilization Pouch Gusseted
The Heat Sealing 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 Heat Sealing 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:

Prevacuum steam; 4 minutes at 132 ℃; 10 minute dry time.
Ethylene oxide: 1 hours at 55 ℃; relative humidity between 40%- 80%; 100% ethylene oxide at a concentration of 740 mg/L, 7 day aeration time at 20℃.

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 Heat Sealing Sterilization Pouch Gusseted are not intended use for any load with lumen/channels and complex device. The maximum wrapped package weight for 300 x 65 x 560 mm size pouch is 1050g, 200 x 33 x 340 mm size pouch is 400g, and 65 x 40 x 254 mm size pouch is 200g.

The sterilization pouch maintains the sterility of the enclosed devices for up to 6 months post sterilization.
Device Size (mm): 65x40x254,70 x 35 x 145,90 x 50 x 155,128 x 50 X 190,137x40x305, 150x50x380, 165x75x295, 200x33x340, 200x98x440,250x60x340,250x60x480,300x65x560.

Heat Sealing Sterilization Pouch Roll Flat
The Heat Sealing 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 Heat Sealing 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:

Prevacuum steam; 4 minutes at 132 ℃; 10 minute dry time.
Ethylene oxide: 1 hours at 55 ℃; relative humidity between 40%- 80%; 100% ethylene oxide at a concentration of 740 mg/L, 7 day aeration time at 20℃.

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 Heat Sealing Sterilization Roll Flat are not intended use for any load with lumen/channels and complex device. The maximum wrapped package weight for 600 x 200 mm size pouch is 910g, 300 x 200 mm size pouch is 450g and 50 x 200 mm size pouch is 100g.

The sterilization roll maintains the sterility of the enclosed devices for up to 6 months post sterilization.
Device Size (mm): 50 x 200,75 x 200,100 x 200,120 x 200,150 x 200,200 x 200,250 x 200,300 x 200,350 x 200, 400 x 200, 500 x 200,600 x 200.

Heat Sealing Sterilization Pouch Roll Gusseted
The Heat Sealing 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 Heat Sealing 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:

Prevacuum steam; 4 minutes at 132 ℃; 10 minute dry time.
Ethylene oxide: 1 hours at 55 ℃; relative humidity between 40%- 80%; 100% ethylene oxide at a concentration of 740 mg/L, 7 day aeration time at 20℃.

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 Heat Sealing Sterilization Roll Gusseted are not intended use for any load with lumen/channels and complex device. The maximum wrapped package weight for 500 x 100 mm size pouch is 750g, 250 x 100 mm size pouch is 375g and 75 x 100 mm size pouch is 100g.

The sterilization roll maintains the sterility of the enclosed devices for up to 6 months post sterilization.
Device Size (mm): 75 x 100,100 x 100,150 x 100,200 x 100,250x 100,300 x 100,350 x 100,400 x 100,500 x 100.

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 withTitle 21, CFR Section 807.92.

The assigned 510(k) Number: K181957

1. Date of Preparation: 07/08/2019

2. Sponsor Identification

Tianchang Jiarui Packaging Material Co., Ltd.
Yeshan Industria Zone, Tianchang City, 239300, Anhui Province of China

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3. Designated Submission Correspondent

Mr. Ray Wang

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4. Identification of Proposed Device

Trade Name: Heat Sealing Sterilization Pouch Flat/Heat Sealing Sterilization Pouch Gusseted/Heat Sealing Sterilization Pouch Roll Flat/Heat Sealing Sterilization Pouch Roll Gusseted
Common Name: Sterilization Pouches & Roll
Model(s):
Heat Sealing Sterilization Pouch Flat
90 x 559mm, 102 x 203 mm, 127 x 381 mm, 130 x 360 mm, 150 x 200 mm, 150 x 300 mm, 152 x 254 mm, 152 x 559 mm, 191 x 330 mm, 200 x 300 mm, 203 x 406 mm, 300 x 400 mm, 305 x 381 mm, 305 x 457 mm, 400 x 500 mm, 300 x 400 mm, 457 x 559 mm, 500 x 600 mm;

Heat Sealing Sterilization Pouch Gusseted
65 x 40 x 254 mm, 70 x 35 x 145 mm, 90 x 50 x 155 mm, 128 x 50 x 190 mm, 137 x 40 x 305 mm, 150 x 50 x 380 mm, 165 x 75 x 295 mm, 200 x 33 x 340 mm, 200 x 98 x 440 mm, 250 x 60 x 340 mm, 250 x 60 x 480 mm, 300 x 65 x 560 mm;

Heat Sealing Sterilization Pouch Roll Flat
75 x 200 mm, 100 x 200 mm, 120 x 200 mm, 150 x 200 mm, 200 x 200 mm, 250 x 200 mm, 300 x 200 mm, 350 x 200 mm, 400 x 200 mm, 500 x 200 mm, 600 x 200 mm;

Heat Sealing Sterilization Pouch Roll Gusseted
75 x 100 mm, 100 x 100 mm, 150 x 100 mm, 200 x 100 mm, 250 x 100 mm, 300 x 100 mm, 350 x 100 mm, 400 x 100 mm, 500 x 100 mm;

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

Intended Use Statement:
Heat Sealing Sterilization Pouch Flat
The ***Heat Sealing 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 ***Heat Sealing 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:
Prevacuum steam; 4 minutes at 132 ℃; 10 minute dry time.
Ethylene oxide: 1 hours at 55 ℃; relative humidity between 40%- 80%; 100% ethylene oxide at a concentration of 740 mg/L, 7 day aeration time at 20℃.

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 ***Heat Sealing Sterilization Pouch Flat*** are not intended use for any load with lumen/channels and complex device. The maximum wrapped package weight for 500 x 600 mm size pouch is 1470 g, 200 x 300 mm size pouch is 300g, 90 x 559 mm size pouch is 250g, and 102 x 203 size pouch is 110g.

The sterilization pouch maintains the sterility of the enclosed devices for up to 6 months post sterilization.

Heat Sealing Sterilization Pouch Gusseted

The ***Heat Sealing 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 ***Heat Sealing 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:

Prevacuum steam; 4 minutes at 132 ℃; 10 minute dry time.

Ethylene oxide: 1 hours at 55 ℃; relative humidity between 40%- 80%; 100% ethylene oxide at a concentration of 740 mg/L, 7 day aeration time at 20℃.

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 ***Heat Sealing Sterilization Pouch Gusseted*** are not intended use for any load with lumen/channels and complex device. The maximum wrapped package weight for 300 x 65 x 560 mm size pouch is 1050g, 200 x 33 x 340 mm size pouch is 400g, and 65 x 40 x 254 mm size pouch is 200g.

The sterilization pouch maintains the sterility of the enclosed devices for up to 6 months post sterilization.

Heat Sealing Sterilization Pouch Roll Flat

The ***Heat Sealing 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 ***Heat Sealing 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:

Prevacuum steam; 4 minutes at 132 ℃; 10 minute dry time.

Ethylene oxide: 1 hours at 55 ℃; relative humidity between 40%- 80%; 100% ethylene oxide at a concentration of 740 mg/L, 7 day aeration time at 20℃.

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 ***Heat Sealing Sterilization Roll Flat*** are not intended use for any load with lumen/channels and

complex device. The maximum wrapped package weight for 600 x 200 mm size pouch is 910g, 300 x 200 mm size pouch is 450g and 50 x 200 mm size pouch is 100g..
The sterilization roll maintains the sterility of the enclosed devices for up to 6 months post sterilization.

Heat Sealing Sterilization Pouch Roll Gusseted

The ***Heat Sealing 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 ***Heat Sealing 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:
Prevacuum steam; 4 minutes at 132 ℃; 10 minute dry time.
Ethylene oxide: 1 hours at 55 ℃; relative humidity between 40%- 80%; 100% ethylene oxide at a concentration of 740 mg/L, 7 day aeration time at 20℃.
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 ***Heat Sealing Sterilization Roll Gusseted*** are not intended use for any load with lumen/channels and complex device. The maximum wrapped package weight for 500 x 100 mm size pouch is 750g, 250 x 100 mm size pouch is 375g and 75 x 100 mm size pouch is 100g.
The sterilization roll maintains the sterility of the enclosed devices for up to 6 months post sterilization.

Device Description

The Heat Sealing Sterilization Pouch/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:
Prevacuum steam: 4 minutes at 132 ℃; 10 minute dry time.
Ethylene oxide: 1 hours at 55 ℃; relative humidity between 40%- 80%; 100% ethylene oxide at a concentration of 740 mg/L, 7 day aeration time at 20℃.

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 Pink to Yellow (EtO) or Blue to Dark Green (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 Sterilization Pouch/Roll is offered in the follow 4 types:
* Heat Sealing Sterilization Pouch Flat;
* Heat Sealing Sterilization Pouch Gusseted;
* Heat Sealing Sterilization Pouch Roll Flat;
* Heat Sealing Sterilization Pouch Roll Gusseted.

The defining characteristics of the 4 types as follows:

Heat Sealing 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.

Heat Sealing Sterilization Pouch Gusseted: These rolls are the same with the Heat Sealing Sterilization Pouch Flat, 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.

Heat Sealing Sterilization Pouch 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 with the sterilization pouches.

Heat Sealing Sterilization Pouch 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.

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. Technological Characteristics

Table 1 General Comparison

ITEM	Subject Device K181957	Predicate Device K143637	Comparison
Indication For Use	The ***Heat Sealing 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 ***Heat Sealing 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: Prevacuum steam; 4 minutes at 132 ℃; 10 minute dry time. Ethylene oxide: 1 hours at 55 ℃; relative humidity between 40%- 80%; 100% ethylene oxide at a concentration of 740 mg/L, 7 day aeration time at 20℃. 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 ***Heat Sealing Sterilization Pouch Flat*** are not intended use for any load with lumen/channels and complex device. The maximum wrapped package weight for 500 x 600 mm size pouch is 1470 g, 200 x 300 mm size pouch is 300g,90x 559mmsize pouch is 250g, and102x203 size pouch is110g. The sterilization pouch maintains the enclosed devices for up to 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 maintains 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 hour EtO sterilization humidity: 50% to 85% RH EtO sterilization concentration:600mg/L Aeration time: 8 hours.	Different
	Heat Sealing Sterilization Pouch Gusseted The ***Heat Sealing 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 ***Heat Sealing 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: Prevacuum steam; 4 minutes at 132 ℃; 10 minute dry time. Ethylene oxide: 1 hours at 55 ℃; relative humidity between 40%- 80%; 100% ethylene oxide at a concentration of 740 mg/L, 7 day aeration time at 20℃. 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 ***Heat Sealing Sterilization Pouch Gusseted*** are not intended use for any load with lumen/channels and complex device. The maximum wrapped package weight for 300 x 65 x 560 mm size pouch is 1050g, 200 x 33 x 340 mm size pouch is400g, and65x40x254 mmsizepouch is200g. The sterilization pouch maintains the enclosed devices for up to 6 months post sterilization.	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.	
	Heat Sealing Sterilization PouchRoll Flat The ***Heat Sealing Sterilization RollFlat*** areintended tobeused toenclose another medical devices that is to be sterilized by ahealth care provider. It is intended to allowsterilization ofthe enclosed medicaldeviceand also to maintain sterility of theenclosed device until used. The ***Heat Sealing Sterilization RollFlat*** areintendedforsterilizationofdental instruments, excludingcomplex devices (endoscopes andinstruments with lumen/channels). The intended sterilizationcycles are listed below:		

	Prevacuum steam; 4 minutes at 132 ℃; 10 minute dry time. Ethylene oxide: 1 hours at 55 ℃; relative humidity between 40%- 80%; 100% ethylene oxide at a concentration of 740 mg/L, 7 day aeration time at 20℃. 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 ***Heat Sealing Sterilization Roll Flat*** are not intended use for any load with lumen/channels and complex device. The maximum wrapped package weight for 600 x 200 mm size pouch is 910g, 300 x 200 mm size pouch is 450g and 50 x200mmsize pouch is 100g. The sterilization pouch maintains the enclosed devices for up to 6 months post sterilization.		
	Heat Sealing Sterilization PouchRoll Gusseted The ***Heat Sealing Sterilization RollGusseted*** are intended to be used to enclose another medical devices that is to be sterilized by ahealth care provider. It is intended to allowsterilization ofthe enclosed medicaldeviceand also to maintain sterility of theencloseddevice until used. The ***Heat Sealing Sterilization RollGusseted***areintended for sterilization of dental instruments, excluding complex devices (endoscopes and instruments with lumen/channels). The intended sterilizationcycles are listed below: Prevacuum steam; 4minutes at 132 ℃; 10 minutedry time. Ethylene oxide: 1 hoursat55℃;relative humidity between 40%-80%;100% ethylene oxide at aconcentrationof 740 mg/L, 7 day aeration time at20℃. The pouch's external chemical ink indicatorsare designed toindicate tothe user that the pouch has undergone either asteam or EtO sterilization process. The ***Heat Sealing Sterilization RollGusseted*** are not intended use for any load		

	with lumen/channels and complex device. The maximum wrapped package weight for 500 x100mm size pouchis750g, 250x 100 mmsize pouch is 375g and 75x100 mm size pouch is 100g. The sterilization pouch maintains the enclosed devices for up to 6 months post sterilization.		
Material Compostion	TopWeb -Medical Porous Paper Bottom Web-MedicalPlastic 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; 4 minutes at 132 ℃; 10 minute dry time. Ethylene oxide: 1 hours at 55 ℃; relative humidity between 40%- 80%; 100% ethylene oxide at a concentration of 740 mg/L, 7 day aeration time at 20℃.	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.	Different
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;	ISO10993-10,Test forIrritation ;ISO10993-10,Testfor Skin sensitization;	Similar
Maintenance of Sterility	6 months	90 Days	Different

or chemical indicator endpoint stability			
Shelf Life	2 years	18 months	Different
Drying Time	10 minutes	25 minutes	Different
Aeration Time	7 days at 20°C	8 hours at 60°C	Different
Chemical Indicator Efficacy	Changed color EtO- Pink to Yellow; Steam- Blue to Dark Green	Changed color EtO- YELLOW to COCOA; Steam- GREEN to PURPLE	Different

7. Non-Clinical Test Conclusion

Non-clinical tests were conducted with the subject device. The test results demonstrated that the subject device met the acceptance criteria. A list on the non-clincial test are provided below:

- ISO 14937:2009 Sterilization of health care products – General requirements or characterization of a sterilizing agent and the development, validation and routine control of a sterilization process for medical device
- ASTM D638-14 Standard Test Method For Tensile Properties of Plastics;
- ASTM F2251-03 Standard Test Method for thickness measurement of flexible packaging material;
- ASTM D1922-03 Standard Test Method for Propagation tear resistance of plastic film and thin sheeting by pendulum method;
- ISO 5636-3:2013 Paper and board – Determination of air permeance (medium range) – Part 3: Bendtsen method;
- ASTM F1140/f1140M-13 Standard Test Methods for internal pressurization failure resistance of unrestrained package;
- ASTM F1608-00 Standard test methods for Microbial Ranking of Porous packaging materials;
- ISO 10993-7:2009 Biological Evaluation of Medical Device – Part 7: Ethylene Oxide Sterilization residuals;
- ISO 11140-1:2009 Sterilization of Health Care Products – Chemical Indicators – Part 1: General Requirements;
- ASTM F1929-12 Standard test methods for detecting seal leaks in porous medical packaging by dye penetration.
- ISO 10993-5:2009 Biological Evaluation of Medical Devices – Part 5: Tests for In Vitro Cytotoxicity;
- ISO 10993-10:2010 Biological Evaluation of Medical Devices – Part 10: Tests for irritation and skin sensitization;
- Shelf Life Validation Test, validate the shelf life performance to the proposed device as real time aging method.
- Sterilization Process Validation Test of Self Sealing Sterilization Pouch for EO and Steam sterilization process
- Verification Test of Self Sealing Sterilization Pouch for EO and Steam Sterilization Process

Name of Test	Purpose of the test	Acceptance criteria	Test Results
Microorganism Penetration testing as ASTM F1608	Microorganism Penetration Test	Retention rate >99.9%	Meet the acceptance criteria
Ethylene oxide residues testing as ISO 10993-7	Ethylene oxide residues	< 4 mg	Meet the acceptance criteria
Internal pressure testing as ASTM	Internal pressure	> 30 kPa	Meet the acceptance criteria

F1140/F1140M	for bursting		
Chemical Indicators performance testing as ISO 11140-1	Chemical Indicators performance	EO indicator, Initial Color: Pink -> Signal Color: Yellow; Steam indicator, Initial Color: Blue -> Signal Color: Dark Green	Meet the acceptance criteria
Tensile strength Testing as ASTM D882	Tensile strength	>7.0 KN/m	Meet the acceptance criteria
Thickness testing as ASTM F2251	Variation in thickness	（138±3）μm	Meet the acceptance criteria
Air Permeability Coefficient Testing as ISO 5636-3	Air Permeability Coefficient	> 8μm/Pa.s	Meet the acceptance criteria
Tear Strength testing as ASTM D1922	Tear Strength	> 500 mN/15mm	Meet the acceptance criteria
Seal strength testing as ASTM F88 / F88M	Seal strength test	>4 N/15mm	Meet the acceptance criteria
Dye Penetration Testing as ASTM F1929	Dye Penetration Test	No Dye Leakage	Meet the acceptance criteria
Dry Validation	Dry time	10 mins	Meet the acceptance criteria

8. Clinical Test Conclusion

No clinical study is included in this submission.

9. Conclusion

The conclusions drawn from the non-clinical tests demonstrate that the device is as safe, as effective, and performs as well as or better than the legally marketed predicate device(K143637)