August 19, 2019

Weihai Xingtai Packaging Products Co.,Ltd.
℅ Ray Wang
Official Correspondent
Beijing Believe-Med Technology Service Co., Ltd.
Rm.912, Building #15, XiYueHui, No.5, YiHe North Rd.
FangShan District
Beijing, 102401 Cn

Re: K183356
Trade/Device Name: Disposable Medical Device Self-seal Sterilization Pouch, Disposable Medical Device Sterilization Reel Pouch
Regulation Number: 21 CFR 880.6850
Regulation Name: Sterilization Wrap
Regulatory Class: Class II
Product Code: FRG
Dated: July 18, 2019
Received: July 22, 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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

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

510(k) Number *(if known)*
K183356

Device Name
Disposable Medical Device Self-seal Sterilization Pouch,Disposable Medical Device Sterilization Reel Pouch

Indications for Use *(Describe)*

Disposable Medical Device Self-seal Sterilization Pouch

The Disposable Medical Device Self-seal Sterilization Pouch are intended to provide health care workers with an effective method to enclose devices intended for sterilization in steam autoclaves.

The intended sterilization cycles are listed below:
Prevacuum steam; 4 minutes at 134 ℃; 10 minute dry time.

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

The Disposable Medical Device Self-seal Sterilization Pouch are not intended use for any load with lumen/channels and complex device. The maximum wrapped package weight for each pouch is 1600g of metal instruments.

Model(s):
57mm×102mm 57mm×130mm 70mm×230mm 83mm×165mm 90mm×260mm 133mm×191mm 133mm×279mm 133mm×290mm 140mm×280mm 140mm×330mm 180mm×330mm 190mm×330mm 190mm×360mm 255mm×380mm 279mm×406mm 300mm×400mm 300mm×474mm 305mm×455mm

Disposable Medical Device Sterilization Reel Pouch

The Disposable Medical Device Sterilization Reel Pouch are intended to provide health care workers with an effective method to enclose devices intended for sterilization in steam autoclaves.

The intended sterilization cycles are listed below:
Prevacuum steam; 4 minutes at 134 ℃; 10 minute dry time.

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

The Disposable Medical Device Self-seal Sterilization Pouch are not intended use for any load with lumen/channels and complex device. The maximum wrapped package weight for each pouch is 1600g of metal instruments.

Model(s):
100mm×100m 150mm×100m 200mm×100m 250mm×100m 300mm×100m 350mm×100m 400mm×100m 50mm×200m 55mm×200m 60mm ×200m 75mm×200m 100mm×200m 125mm×200m 150mm×200m 200mm×200m 225mm×200m 250mm×200m 300mm×200m 350mm×200m 400mm×200m

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(k) Summary

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

The assigned 510(k) Number: K183356

1. Date of Preparation: 08/01/2019
2. Sponsor Identification

Weihai Xingtai Packaging Products Co., Ltd.
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3. Designated Submission Correspondent

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4. Identification of Proposed Device

Trade Name: Disposable Medical Device Self-seal Sterilization Pouch,Disposable Medical Device Sterilization Reel Pouch

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

Predicate devices:
510(k) Number: K162258 Device Name: Self Sealing Sterilization Pouches (primary predicate)
510(k) Number: K102158 Device Name: SIGMA Sterilization Pouch and Roll

5. Device Description

The design information as mentioned in this section is to provide the clear description for the devices included in the 510(k) submission. Basically the information was provided according to the FDA guidance Premarket Notification [510(k)] Submissions for Medical Sterilization Packaging Systems in Health Care Facilities; Draft Guidance for Industry and FDA.

There are 2 models of the Sterilization Pouches in this application with different physical specification. The Disposable Medical Device Self-seal Sterilization Pouch is made from a medical grade plastic film that is heat sealed on three sides. The forth side has an adhesive strip that is used to seal the pouch. It is a strip to cover the adhesive area and is released before seal the pouch. The medical grade paper conforms to recognized material standards and can be sterilized by steam or ethylene oxide gas. The Process Indicators Ink printed on the medical grade paper will exhibit a color change after the pouch is exposed to steam.

The Disposable Medical Device Sterilization Reel Pouch are made from a medical grade paper and plastic (PP/PET) film that are heat sealed on opposite two sides. It will be cut to suitable length and the opened sides will be heat-sealed. The Process Indicators Ink printed on the medical grade paper will exhibit a color change after the pouch is exposed to steam.

Disposable Medical Device Self-seal Sterilization Pouch Model(s):
57mm×102mm 57mm×130mm 70mm×230mm 83mm×165mm 90mm×260mm 133mm×191mm
133mm×279mm 133mm×290mm 140mm×280mm 140mm×330mm 180mm×330mm
190mm×330mm 190mm×360mm 255mm×380mm 279mm×406mm 300mm×400mm
300mm×474mm 305mm×455mm

Disposable Medical Device Sterilization Reel Pouch Model(s):
100mm×100m 150mm×100m 200mm×100m 250mm×100m 300mm×100m 350mm× 100m
400mm × 100m 50mm × 200m 55mm × 200m 60mm × 200m 75mm × 200m 100mm×200m
125mm×200m 150mm×200m 200mm×200m 225mm×200m 250mm ×200m
300mm×200m 350mm×200m 400mm×200m

Intended Use Statement:
Disposable Medical Device Self-seal Sterilization Pouch
The Disposable Medical Device Self-seal Sterilization Pouch is intended to provide healthcare workers with an effective method to enclose devices intended for sterilization in steam autoclaves.

The intended sterilization cycle is listed below:
Prevacuum steam; 4 minutes at 134℃; 10 minute dry time.

The pouch's external chemical ink indicator is designed to indicate to the user that the pouch has undergone a steam sterilization process.

The Disposable Medical Device Self-seal Sterilization Pouch is not intended use for any load with lumen/channels and complex device. The maximum wrapped package weight for each pouch is 1600g of metal instruments.

Disposable Medical Device Sterilization Reel Pouch
The Disposable Medical Device Sterilization Reel Pouch is intended to provide health care

workers with an effective method to enclose devices intended for sterilization in steam autoclaves.

The intended sterilization cycle is listed below:
Prevacuum steam; 4 minutes at 134℃; 10 minute dry time.

The pouch's external chemical ink indicator is designed to indicate to the user that the pouch has undergone a steam sterilization process.

The Disposable Medical Device Self-seal Sterilization Pouch is not intended use for any load with lumen/channels and complex device. The maximum wrapped package weight for each pouch is 1600g of metal instruments.

6. Technological Characteristics

Predicate Device - 510(k) Number: K162258 Device Name: Self Sealing Sterilization Pouches

Reference Device - 510(k) Number: K102158 Device Name: SIGMA Sterilization Pouch and Roll

Proposed Device: K183356	Predicate Device: K162258	Reference Device: K102158
Indication For Use		
Disposable Medical Device Self-seal Sterilization Pouch The Disposable Medical Device Self-seal Sterilization Pouch are intended to provide health care workers with an effective method to enclose devices intended for sterilization in steam auto claves. The intended sterilization cycles are listed below: Prevacuum steam; 4 minutes at 134 ℃; 10 minute dry time. The pouch's external chemical ink indicators are designed to indicate to the user that the pouch has undergone either a steam sterilization process.	The Self Sealing Sterilization Pouches 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 Self Sealing Sterilization Pouches 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	The SIGMA sterilization pouch and roll are intended to provide health care workers with an effective method to enclose devices intended for sterilization in steam auto claves and via Ethylene Oxide (EO). The recommended steam sterilization cycle parameters are 30 minutes at 121 ℃. The recommended EO 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 3 years 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 EO sterilization process.
Disposable Medical Device Sterilization Reel Pouch The Disposable Medical Device Sterilization Reel Pouch are intended to provide health care workers with an effective method to enclose devices intended for sterilization in		

steam auto claves. The Disposable Medical Device Sterilization Reel Pouch is 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 134 ℃; 10 minute dry time. The pouch's external chemical ink indicators are designed to indicate to the user that the pouch has undergone either a steam sterilization process	indicators are designed to indicate to the user that the pouch has undergone either a steam or EtO sterilization process. The Self Sealing sterilization Pouches are not complex device. The maximum wrapped package weight for each pouch is 540g or 1.19 lbs. The sterilization pouch maintains the enclosed devices up until 6 months post sterilization.	

Technical Characteristics

ITEM	Proposed Device: K183356	Predicate Device: K162258	Reference Device: K102158
Material Composition	Top Web - Medical Porous Paper Bottom Web - Medical Plastic film(PP) Steam indicator ink-Process Indicators	Top Web - Medical Porous Paper Bottom Web - Medical Plastic film(CPP) EtO gas indicator ink-Process Indicators Steam indicator ink-Process Indicators	Self-sealing sterilization pouches: These pouches are made from a medical grade plastic film that is heat sealed on three side. The forth side has an adhesive strip that is used to seal the pouch .Release paper used in the pouch is laminated sheet with composing structure of PE/paper/ PE.it is a strip to cover the adhesive area and is release before seal the pouch. The medical grade paper conforms to recognized material standards and can be sterilized by steam or EO gas. The process indicator INK printed on the medical grade paper will exhibit a color change after the pouch is exposed to steam or EO gas
Sterilization Cycles	Prevacuum steam; 4 minutes at 134 ℃; 10 minute dry time.	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 steam sterilization cycle parameters are 30 minutes at 121℃. The recommended EO sterilization cycle is 4 hours at 55 t with a relative humidity between50-85% and a sterilant concentration of 600 mg/L
Configuration/ Dimension	Various Sizes	Various Sizes	Various Sizes
Air Permeance	The maximum equivalent pore size diameter shall not exceed 50um	The maximum equivalent pore size diameter shall not exceed 50um	NA
Material Compatibility	After sterilization, the materials were not degraded	After sterilization, the materials were not degraded	After sterilization, the materials were not degraded

ITEM	Proposed Device: K183356	Predicate Device: K162258	Reference Device: K102158
Maintenance of Sterility	6 months	6 months	1 year
Shelf Life	2 years	2 years	3 years
Drying Time	10 minutes	10 minutes	30 minute
Chemical Indicator Efficacy	Steam Sterilization Indicating Ink Initial Color: Blue -> Signal Color: Ash Black	Changed color EtO- Pink to Yellow;Steam- Blue to black	Changed color EtO- Yellow; Steam- Black

7. Non-Clinical Testing

Non clinical tests were conducted to verify that the proposed device met all design specifications. The test results demonstrated that the proposed device complies with the following standards:

- ~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 11140-1:2009 Sterilization of Health Care Products – Chemical Indicators – Part 1: General Requirements;
- ASTM F1980-07 Standard guide for accelerated aging of sterile barrier systems for medical device;
- 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.
- Steam Sterilization Process Validation and Sterilization test report:
    - Half cycle overkill validation of the claimed steam sterilization cycle: Challenge loads consisted of scalers, hemostatic forceps and tooth probes. No cavities or complex devices. All loads showed no growth at 1/2 cycle.
    - Dry time validation: Full cycle sterilization testing showed samples to be free of visible moisture with no signification weight gain following sterilization and stated dry time.

8. Clinical Testing:

No clinical study is included in this submission.

9. Conclusion

The conclusions drawn from the nonclinical tests demonstrate that the Disposable Medical Device Self-seal Sterilization Pouch,Disposable Medical Device Sterilization Reel Pouch is as safe, as effective, and performs as well as or better than the legally marketed device.