89DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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April 28, 2017

Tianchang Jiarui Packaging Material Co., Ltd.
% Ray Wang
General Manager
Beijing Believe Technology Service Co., Ltd.
5-1206, Build 332, DaFangJu, No. 25 BanBiDian Rd.,
TongZhou District
Beijing, 101121 CN

Re: K162258
Trade/Device Name: Self Sealing Sterilization Pouches
Regulation Number: 21 CFR 880.6850
Regulation Name: Sterilization Wrap
Regulatory Class: Class II
Product Code: FRG, JOJ
Dated: March 8, 2017
Received: March 13, 2017

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. 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); good manufacturing practice requirements as set forth in

the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely,

Michael J. Ryan -S

for Tina Kiang, Ph.D.
Acting Director
Division of Anesthesiology,
General Hospital, Respiratory,
Infection Control, and Dental Devices
Office of Device Evaluation
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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K162258

Device Name
Self Sealing Sterilization Pouches

Indications for Use *(Describe)*
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 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 intended use for any load with lumen/channels and 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.

The pouches are available in the following sizes:
Model(s): 57 x 102mm, 57 x 130 mm, 70 x 255 mm, 83 x 165 mm, 90 x 260 mm, 133 x 191 mm, 133 x 279 mm, 133 x 290 mm, 140 x 280 mm, 140 x 330 mm, 180 x 330 mm, 190 x 330 mm, 190 x 360 mm, 255 x 380 mm, 279 x 406 mm, 300 x 400 mm, 300 x 474 mm, 305 x 457 mm;

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) safety and effectiveness information is being submitted in accordance with requirements of SMDA 1990 and Title 21, CFR Section 807.92.

The assigned 510(k) Number: K162258

1. Date of Preparation: 2017-4-24

2. Sponsor Identification

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3. Designated Submission Correspondent

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4. Identification of Proposed Device

Trade Name: Self Sealing Sterilization Pouches
Common Name: Sterilization Pouches
Model(s): 57 x 102mm, 57 x 130 mm, 70 x 255 mm, 83 x 165 mm, 90 x 260 mm, 133 x 191 mm, 133 x 279 mm, 133 x 290 mm, 140 x 280 mm, 140 x 330 mm, 180 x 330 mm, 190 x 330 mm, 190 x 360 mm, 255 x 380 mm, 279 x 406 mm, 300 x 400 mm, 300 x 474 mm, 305 x 457 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:
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 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 intended use for any load with lumen/channels and 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.
The pouches are available in the following sizes:

Model(s): 57 x 102mm, 57 x 130 mm, 70 x 255 mm, 83 x 165 mm, 90 x 260 mm, 133 x 191 mm, 133 x 279 mm, 133 x 290 mm, 140 x 280 mm, 140 x 330 mm, 180 x 330 mm, 190 x 330 mm, 190 x 360 mm, 255 x 380 mm, 279 x 406 mm, 300 x 400 mm, 300 x 474 mm, 305 x 457 mm;

Device Description

There are 18 models of the Self Sealing Sterilization Pouches in this application with different physical specification.

These pouches are made from a medical grade paper and plastic (CPP/PET) film that are heat sealed on three sides. The forth side has an adhesive strip that is used to seal the pouch. Release paper used in the pouch is a laminated sheet with composing structure of PE/paper/PE. 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 indicators printed on the medical grade paper will exhibit a color change (EtO- Pink to Yellow/Steam- Blue to Dark Green) after the pouch is exposed to steam or ethylene oxide gas.
The validated maintenance of sterility period is 6 months.

5. Identification of Predicate Device(s)

Predicate Device

510(k) Number: K143637
Product Name: Winner Self Seal Sterilization Pouch
Model Name: U&U Medical Technology Co., Ltd.

The comparison table is shown in subsection 8.

6. Non-Clinical Test Conclusion

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:

- 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 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.
- 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

7. Clinical Test Conclusion

No clinical study is included in this submission.

8. Substantially Equivalent (SE) Comparison

Table 1 General Comparison

ITEM	Proposed Device	Predicate Device	Remark
Indication For Use	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 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 intended use for any load with lumen/channels and 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. The pouches are available in the following sizes: Model(s): 57 x 102mm, 57 x 130 mm, 70	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.	Similar

	x 255 mm, 83 x 165 mm, 90 x 260 mm, 133 x 191 mm, 133 x 279 mm, 133 x 290 mm, 140 x 280 mm, 140 x 330 mm, 180 x 330 mm, 190 x 330 mm, 190 x 360 mm, 255 x 380 mm, 279 x 406 mm, 300 x 400 mm, 300 x 474 mm, 305 x 457 mm;		
Material Compostion	Top Web - Medical Porous Paper Bottom Web - Medical Plastic film(CPP) Bottom Web - Medical two-sided adhesive tape EtO gas indicator ink-Process Indicators Steam indicator ink-Process Indicators	Top Web - Medical Porous Paper Bottom Web - Medical Plastic film(CPP) Bottom Web - Medical two-sided adhesive tape EtO gas indicator ink-Process Indicators class 1 Steam indicator ink-Process Indicators class 1	SE
Sterilization Cycles	The recommended gravity steam sterilization cycle parameters is Prevacuum steam 4 minutes at 132 ℃; 10 minute dry time. The recommended EtO sterilization cycle is 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.	Similar
Configuration/ Dimension	Min. 57 x 102 mm Max. 305 x 457 mm	Width: ±0.1″″ Length ± 0.2″″	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, and met the acceptance criteria	Use ASTM 1608 method, and met the acceptance criteria	SE
Material Compatibility	After sterilization, the materials were not degraded	After sterilization, the materials were not degraded	SE
Biocompatibility	Meet ISO 10993-1	Meet ISO10993-1	SE
Maintenance of Sterility	6 months	90 Days	Similar
Shelf Life	2 years	18 months	Similar
Drying Time	10 minutes	25 minutes	Similar
Aeration Time	7 days at 20°C	8 hours at 60°C	Similar
Chemical Indicator Efficacy	Changed color EtO- Pink to Yellow; Steam- Blue to Dark Green	Changed color EtO- YELLOW to COCOA; Steam- GREEN to PURPLE	Similar

Analysis for difference

The noted differences above do not change the intended use of the device or raise new safety and effectiveness concerns.

9. Substantially Equivalent (SE) Conclusion

Based on the comparison and analysis above, the subject device is determined to be Substantially Equivalent (SE) to the predicate device.