April 15, 2020

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: K193561
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, JOJ
Dated: March 13, 2020
Received: March 16, 2020

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 Christopher K. Dugard, MS
Acting Assistant Director
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)*
K193561

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 auto claves and via Ethylene Oxide (EO).

The intended sterilization cycles are listed below:
Prevacuum steam; 4 minutes at 134 ℃; 10 minute dry time.
Ethylene oxide: 1 hours at 55 ℃; relative humidity between 40%- 80%;100% ethylene oxide at dosage of 759mg/L, 12 hours aeration time at 55℃.

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 Disposable Medical Device Self-Seal Sterilization Pouch are not intended use for any load with lumen/channels and complex device.

The dimension range for each of the weights used in testing:
Size 57×102mm: Maximum load weight 400g
Size 140x280mm: Maximum load weight 900g
Size 305×455mm: Maximum load weight 1600g

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 auto claves and via Ethylene Oxide (EO).

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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 Disposable Medical Device Self-Seal Sterilization Pouch are not intended use for any load with lumen/channels and complex device.

The dimension range for each of the weights used in testing

Size 50mm×200mm：Maximum load weight 400g

Size 300mm×200mm：Maximum load weight 900g

Size 400mm×200mm：Maximum load weight 1600g

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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