March 10, 2022

Weihai Hongyu Nonwoven Fabric Products 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, Bejing 102401
China

Re: K220133
Trade/Device Name: Sterilization Wraps
Regulation Number: 21 CFR 880.6850
Regulation Name: Sterilization Wrap
Regulatory Class: Class II
Product Code: FRG
Dated: January 12, 2022
Received: January 18, 2022

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,

Colin O’Neill, M.B.E.
Assistant Director
DHT6C: Division of Spinal Devices
OHT6: Office of Orthopedic 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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K220133

Device Name
Sterilization Wraps

Indications for Use *(Describe)*
Sterilization Wraps is intended to be used to enclose another medical device that is to be sterilized by a health care provider using:
• Pre-vacuum steam at 270°F/132°C for 4 minutes

Types of medical devices to be sterilized in the pre-vacuum cycle:
General purpose reusable metal and nonmetal devices(No lumen) including devices with stainless steel diffusion-restricted spaces such as forceps and scissors, as well as other general medical instruments having mated surfaces, knurled areas etc.

The size of the Devices to be sterilized shall allow Sterilization Wraps pack and form a closed space. Validated for dry time is 30 minutes for Sterilization Wraps.

Color of wrap: Blue
Size of wrap: 48 in x 48 in

The maximum validated weight of load for Sterilization Wraps is 12kg.

The wrap is intended to allow sterilization of the enclosed medical device(s) and also to maintain sterility of the enclosed device(s) until used.

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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The assigned 510(k) Number: K220133

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.

1. Date of Preparation: 03/01/2022

2. Sponsor Identification

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3. Designated Submission Correspondent

Mr. Ray Wang

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4. Identification of Proposed Device

Trade Name: Sterilization Wraps
Common Name: Sterilization Wrap

Regulatory Information
Classification Name: Sterilization wrap (21 CFR part 880.6850)
Classification: 2
Product Code: FRG - Wrap, sterilization
Regulation Number: 21 CFR 880.6850
Review Panel: General Hospital

Indication For Use Statement:
Sterilization Wraps is intended to be used to enclose another medical device that is to be sterilized by a health care provider using:

- Pre-vacuum steam at 270°F/132°C for 4 minutes

Types of medical devices to be sterilized in the pre-vacuum cycle:
General purpose reusable metal and nonmetal devices(No lumen) including devices with stainless steel diffusion-restricted spaces such as forceps and scissors, as well as other general medical instruments having mated surfaces, knurled areas etc.

The size of the Devices to be sterilized shall allow Sterilization Wraps pack and form a closed space. Validated for dry time is 30 minutes for Sterilization Wraps.

Color of wrap: Blue
Size of wrap: 48 in x 48 in

The maximum validated weight of load for Sterilization Wraps is 12kg.

The wrap is intended to allow sterilization of the enclosed medical device(s) and also to maintain sterility of the enclosed device(s) until used.

5. Identification of Predicate Device(s)

Predicate Device
510(k) Number: K182656
Product Name: JAMBRO Single Core A Sterilization Wrap
Manufacturer: Jiangsu Zhande Medical Supplies Co., Ltd

6. Non-Clinical Test Conclusion

Non clinical tests were conducted to verify that the proposed device met all design specifications as

was Substantially Equivalent (SE) to the predicate device. The test results demonstrated that the proposed device complies with the following standards:

- 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.
- ANSI AAMI ISO 17665-1:2006/(R)2013 Sterilization of health care products -- Moist heat -- Part 1: Requirements for the development, validation, and routine control of a sterilization process for medical devices
- AATCC 127-18 Test Method for Water Resisitance: Hydrostatic Pressure
- ISO 11607:2019 Packaging for terminally sterilized medical devices
- ASTM D5587-15 Standard Test Method for Tearing Strength of Fabrics by Trapezoid Procedure
- ASTM D5034-2009 Standard Test Method for Breaking Strength and Elongation of Textile Fabrics (Grab Test)
- ASTM D737-18 Standard test method for air permeability
- ASTM D3776/D3776M Standard test method for mass per unit area (weight) of fabric
- ASTM D3786/D3786M-18 Standard test method for Bursting Strength of Textile Fabrics-Diaphragm Bursting Strength Tester Method
- ASTM F2101-14 Standard Test Method for Evaluating the Bacterial Filtration Efficiency (BFE) of Medical Face Mask Materials, Using a Biological Aerosol of Staphylococcus aureus
- United States Pharmacopeia < 71 >
- ANSI/ AAMI ST79:2017, Comprehensive guide to steam sterilization and sterility assurance in health care facilities

7. Clinical Test Conclusion

No clinical study is included in this submission.

8. Substantially Equivalent (SE) Comparison

ITEM	Proposed Device	Predicate Device K182656	Remark
Intended Use	Sterilization Wraps is intended to be used to enclose another medical device that is to be sterilized by a health care provider using: • Pre-vacuum steam at 270°F/132°C for 4 minutes Types of medical devices to be sterilized in the pre-vacuum cycle: General purpose reusable metal and nonmetal devices(No lumen) including devices with stainless steel diffusion-restricted spaces such as forceps and scissors, as well as other general medical instruments having mated surfaces, knurled areas etc. The size of the Devices to be sterilized shall allow Sterilization Wraps pack and form a closed space. Validated for dry times of 30 minutes for Sterilization Wraps. Color of wrap: Blue Size of wrap: 48 in x 48 in	JAMBRO Single Core A is intended to be used to enclose another medical device that is to be sterilized by a health care provider using: Gravity steam at 250°F/121°C for 30 minutes Pre-vacuum steam at 270°F/132°C for 4 minutes Types of medical devices to be sterilized in the gravity cycle; General purpose non-lumened reusable metal and nonmetal devices including devices with stainless steel diffusionrestricted spaces such as the hinged portion of forceps and scissors, as well as other general medical instruments having mated surfaces, knurled areas etc. Types of medical devices to be sterilized in the pre-vacuum cycle are; General purpose reusable metal and nonmetal devices including devices with stainless steel diffusion-restricted spaces such as the hinged portion of forceps and scissors, as well as other eneral medical instruments having mated surfaces, knurled areas etc. Up to 2 single channel stainless steel lumened devices of the	SIMILAR

	The maximum validated weight of load for Sterilization Wraps is 12kg. The wrap is intended to allow sterilization of the enclosed medical device(s) and also to maintain sterility of the enclosed device(s) until used.	following dimensions; An inside diameter of 3 mm or larger and a length of 400 mm or shorter; Color of wrap: Blue Size of wrap: 48 in x 48 in The maximum validated weight of load for JAMBRO Single Core A is 25 lbs. The wrap is intended to allow sterilization of the enclosed medical device(s) and also to maintain sterility of the enclosed device(s) until used.	
Product Code	FRG	FRG	SAME
Regulation Number	880.6850	880.6850	SAME
Use	Single Use; Disposable	Single Use; Disposable	SAME
Design Features	Sterilization Wraps is a 63gsm, latex-free, 3-layer (SMS) non-woven sterile wrap, manufactured with spun-bonded / meltblown polypropylenem. Sterilization Wraps provides a strong barrier which protects against cuts, tears with particularly heavy orthopedic sets. Sterilization Wraps is designed to be implemented as an outer sterilization wrap which can be used in combination with Clinipak choice.	The JAMBRO® Single Core A Sterilization wrap are square nonwoven sheets produces using a three-layer SMS (spunbond-meltblown-spunbond) process. • JAMBRO® Single Core A Consists of single sheets of SMS wrap, where two sheets are used together for the sequential wrapping of one or a collection of medical devices that will be sterilized following standard healthcare practices.	SIMILAR
Materials	Sterilization Wraps is made of polypropylene and blue pigment by non-woven process.	The JAMBRO® Single Core A Sterilization wrap are composed of polypropylene with blue pigments and an anti-static treatment. The JAMBRO® Single Core A Sterilization wrap	SAME

		allows a sterilized package of medical devices to be opened aseptically.	
Prescription vs. OTC	OTC	OTC	SAME
Color	Blue	Blue	SAME
Wrapping Technique	Sequential	Sequential	SAME
Sterilization	• Pre-vacuum steam at 270°F/132°C for 4 minutes • Drying time: 30 minutes	• pre-vacuum steam at 270ºF/132ºC for 4 minutes • Gravity Steam at 250ºF/121ºC for 30 minutes • Drying time: 30 minutes	SAME
Size	48 in X 48 in	48 in X 48 in	SAME
Maintenance of Package Sterility	90 days	90 days	SAME
Shelf Life	18 months	18 months	SAME

9. Performance data

For the sterilization wrap performance testing, the following standards were utilized to demonstrate that the device met the acceptance criteria in the following standards below:

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.

ANSI AAMI ISO 17665-1:2006/(R)2013 Sterilization of health care products -- Moist heat -- Part 1: Requirements for the development, validation, and routine control of a sterilization process for medical devices

AATCC 127-18 Test Method for Water Resisitance: Hydrostatic Pressure

ISO 11607:2019 Packaging for terminally sterilized medical devices

ASTM D5587-15 Standard Test Method for Tearing Strength of Fabrics by Trapezoid Procedure

ASTM D5034-2009 Standard Test Method for Breaking Strength and Elongation of Textile Fabrics (Grab Test)
ASTM D737-18 Standard test method for air permeability
ASTM D3776/D3776M Standard test method for mass per unit area (weight) of fabric
ASTM D3786/D3786M-18 Standard test method for Bursting Strength of Textile Fabrics-Diaphragm Bursting Strength Tester Method
ASTM F2101-14 Standard Test Method for Evaluating the Bacterial Filtration Efficiency (BFE) of Medical Face Mask Materials, Using a Biological Aerosol of Staphylococcus aureus
United States Pharmacopeia < 71 >
ANSI/ AAMI ST79:2017, Comprehensive guide to steam sterilization and sterility assurance in health care facilities

Following testing have been performed:

Table 11-2

Study	Standards	Description/Criteria	Results
Sterilization Validation - Steam PREVACUUM	ANSI AAMI ISO 17665-1:2006/(R)2013	A method of steam sterilization was validated to a sterility assurance level (SAL) of 10^{-6}	Pass
Sterilant Penetration - Steam PREVACUUM	ANSI AAMI ISO 17665-1:2006/(R)2013	The testing details the methods used in determining the internal temperature profile for wrapped sterilization packs when processed in a steam sterilization pre-vacuum cycle at 132°C (270°F) for four (4) minutes exposure.	Testing has demonstrated adequate sterilant penetration
Validation - Dry Time	ANSI AAMI ISO 17665-1:2006/(R)2013	Determining the proper drying time required	Test samples meet or exceed the minimum criteria for dry time.
90 Day Real Time Maintenance of Sterility Validation -Steam PREVACUUM	AATCC 127-18 ISO 11607:2019 ASTM D3776/D3776M ASTM D3786/D3786M-18	The study details the methods used in verifying the test samples can maintain the integrity of its contents for an extended period of time following exposure to a steam sterilization	No growth

	ASTM D5587-15 ASTM D5034-2009 ASTM D737-18 ASTM F2101-14	process.	
Package Integrity Test - Steam PREVACUUM	AATCC 127-18 ISO 11607:2019 ASTM D5587-15 ASTM D5034-2009	The testing details the methods of the test sample in maintaining package integrity.	The subject wrap, were found to be effective barriers when processed in a Steam Pre-Vacuum cycle.
Bacterial Filtration Efficiency (BFE) of Non-Woven Sterilization Wrap When Processed In a Steam Sterilization Cycle	ISO 11607:2019 ASTM F2101-14	BFE testing is a type of test used to determine the efficiency of filter materials to provide protection against microbial organisms.	Pass
Dimension testing	ISO 11607:2019	48 in X 48 in	Pass
Weight testing	ASTM D3776/D3776M	According to the standard test, the weight should meet the requirements	Pass
Air Permeability Test	ASTM D737	Air permeability should meet the requirements of ASTM D737.	Pass
Package Integrity	AATCC 127-18 ISO 11607:2019 ASTM D5587-15 ASTM D5034-2009	The purpose of the physical properties testing was to demonstrate passing results for the physical properties （contain Hydrostatic pressure, Weight, Bursting Strength, Tear Resistance, Tensile Strength）for the wrap.	The physical properties testing met the acceptance criteria and demonstrated passing results
Shelf Life Testing	AATCC 127-18 ISO 11607:2019 ASTM D3776/D3776M	Whole package integrity test of real time shelf life samples	Sterilization Wraps was capable of maintaining sterility and package integrity (when used as a steam

	ASTM D3786/D3786M-18 ASTM D5587-15 ASTM D5034-2009 ASTM D737-18 ASTM F2101-14		sterilization wrapper) following an approximate 18 month period of real time shelf life prior to being sterilized in the steam sterilization cycles
Cytotoxicity testing	ISO 10993-5: 2009	No cytotoxic potential	Pass
Irritation testing	ISO 10993-10: 2010	No irritation on the skin	Pass
Sensitization testing	ISO 10993-10: 2010	No skin sensitization	Pass

10. Substantially Equivalent (SE) Conclusion

Based on the nonclinical tests performed, the subject device is as safe, as effective, and performs as well as the legally marketed predicate device, JAMBRO Single Core A Sterilization Wrap cleared under K182656.