June 11, 2019

Jiangsu Zhande Medical Supplies Co., Ltd
℅ Jigar Shah
Consultant
mdi Consultants, Inc.
55 Northern Blvd
Great Neck, New York 11021

Re: K182656
Trade/Device Name: JAMBRO Single Core A Sterilization wrap
Regulation Number: 21 CFR 880.6850
Regulation Name: Sterilization Wrap
Regulatory Class: Class II
Product Code: FRG
Dated: March 12, 2019
Received: March 14, 2019

Dear Jigar Shah:

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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/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 F. Claverie-Williams, MS
Assistant Director,
THT4B2: Disinfection Reprocessing and Personal Protection
Acting Assistant Director,
THT4B1: Sterility Devices
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)*
K182656

Device Name
JAMBRO Single Core A Sterilization wrap

Indications for Use *(Describe)*
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

Gravity steam and Pre-vacuum steam sterilization:
Validated for dry times of 30 minutes for JAMBRO Single Core A

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 diffusion-restricted 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 general medical instruments having mated surfaces, knurled areas etc.
- Up to 2 single channel stainless steel lumened devices of the 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.

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

The assigned 510(k) number is K182656

I. SUBMITTER

Jiangsu Zhande Medical Supplies Co., Ltd
Nanjing Binjiang Economic Development Park
#719 Shengan Avenue, 1/F Building H1
Jiangsu, Nanjing, China 211178

Date Summary Prepared: June 3, 2019

Contact Person: Ms. Chanjuan Xu

II. DEVICE

Name of Device: JAMBRO® Single Core A Sterilization wrap
Common or Usual Name: Sterilization Wrap
Classification Name: Sterilization Wrap
Regulatory Class: 21 CFR Part 880.6850 Class II
Product Code: FRG

III. PREDICATE DEVICE

Ahlstrom Nonwovens LLC's Reliance® Solo Sterilization Wrap, Reliance® Tandem Sterilization Wrap, K160755

IV. DEVICE DESCRIPTION

JAMBRO Single Core A is a 63gsm, latex-free, 3-layer (SMS) non-woven sterile wrap, manufactured with spun-bonded / meltblown polypropylenem. JAMBRO Single Core A provides a strong barrier which protects against cuts, tears with particularly heavy orthopedic sets. JAMBRO Single Core A is designed to be implemented as an outer sterilization wrap which can be used in combination with Clinipak choice.

The Maximum Recommended Wrapped Package Content Weights for the JAMBRO Single Core A (63g/m^2) is 25 lbs.

The Intended Load for the JAMBRO Single Core A (63g/m^2) is moderate to heavy weight package (e.g., general use medical instruments) and the JAMBRO Single Core A can maintain sterility of sterilized devices for 90 days.

V. INDICATIONS FOR USE

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

Gravity steam and Pre-vacuum steam sterilization:
Validated for dry times of 30 minutes for JAMBRO Single Core A

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 diffusion-restricted 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 general medical instruments having mated surfaces, knurled areas etc.
- Up to 2 single channel stainless steel lumened devices of the 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.

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

The JAMBRO Single Core A sterilization wrap is similar to the RELIANCE Solo sterilization wrap, K160755. The following Comparison Chart is outlined:

Comparison Chart

Device Characteristic	Proposed Device	Predicate Device	Comparison
Product Name	JAMBRO® Single Core A Sterilization wrap	Reliance® Solo Sterilization Wrap, Reliance® Tandem Sterilization Wrap	
510(k) Reference	K182656	K160755	
Product Owner	Jiangsu Zhande Medical Supplies Co., Ltd	Ahlstrom Nonwovens LLC	
Product Code	FRG	FRG	Similar
Indications for Use	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 diffusion-restricted 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 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.	Ahlstrom Reliance® Tandem and Solo Sterilization Wraps are intended to be used to enclose another medical device that is to be sterilized by a healthcare provider via the following: • Pre-vacuum Steam 270°F/132°C for 4 minutes • Gravity Steam 250°F/121°C for 30 minutes • 100% Ethylene Oxide (EO) with a concentration of 725-735 mg/L @ 131°F/55°C and 40%-80% relative humidity for 60 minutes • Advanced Sterilization Products (ASP) STERRAD® 100S • Advanced Sterilization Products (ASP) STERRAD® 100NX (Standard, Express and Flex cycles) • STERIS Amsco® V-PRO 1, STERIS Amsco® V-PRO 1 Plus, STERIS Amsco® V-PRO maX Low Temperature Sterilization Systems (Lumen, Non Lumen and Flexible Cycles) The wrap is intended to allow sterilization of the enclosed medical device(s) and maintain sterility of the enclosed device(s) until used.	Similar

Regulation Number	21 CFR 880.6850	21 CFR 880.6850	Similar
Design Features	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.	The Reliance® Tandem and Solo Sterilization Wraps are square or rectangular nonwoven sheets produced using a three-layer SMS (spunbond-meltblown-spunbond) process. The Reliance® SMS Sterilization Wraps are separated into two distinct product offerings: • Reliance® Tandem: 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. • Reliance® Solo: Consists of two sheets of SMS wrap, ultrasonically bonded together along two edges for convenient simultaneous wrapping of one or a collection of medical devices that will be sterilized following standard healthcare practices.	Similar
Size and color	48”X 48” Blue	9”x9” to 54”x90” Blue or Green	similar
Materials	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 allows a sterilized package of medical devices to be opened aseptically.	The Reliance® Tandem and Solo Sterilization Wraps are composed of polypropylene with the addition of blue or green pigment and an anti-static treatment. Reliance® Tandem and Solo Sterilization Wraps allow a sterilized package of medical devices to be opened aseptically.	Similar
Prescription vs. OTC	OTC	OTC	Similar

Sterilization	• pre-vacuum steam at 270ºF/132ºC for 4 minutes • Gravity Steam at 250ºF/121ºC for 30 minutes • Drying time: 30 minutes	• pre-vacuum steam at 270ºF/132ºC for 4 minutes • Drying time: Reliance® Tandem and Solo Models T100/S100, T200/S200, T300/S300: 20 minutes Reliance® Tandem and Solo Models T400/S400, T500/S500, T600/S600: 30 minutes • 100% ethylene oxide (EO) with a concentration of 725 -735 mg/L at 131ºF/55ºC and 40% - 80% relative humidity for 60 minutes • Gravity Steam at 250ºF/121ºC for 30 minutes • Advanced Sterilization	Similar
Wrapping Technique	Sequential	Sequential/simultaneous double wrapping	Similar
Disposable vs. Non-Disposable	Disposable	Disposable	Similar
Single Use vs. Reusable	Single Use	Single Use	Similar
Biocompatibility	Cytotoxicity ISO 10993-5	Cytotoxicity ISO 10993-5	Similar
Maintenance of Package Sterility	90 days	90 days	Similar
Shelf Life	18 months	NA	Similar

VII. 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:

ANSI/ AAMI ST77:2013, Containment devices for reusable medical device sterilization

ANSI/ AAMI ST79:2017, Comprehensive guide to steam sterilization and sterility assurance in health care facilities

ANSI/ AAMI/ ISO 14937:2009/(R) 2013, Sterilization of health care products – General requirements for characterization of a sterilizing agent and the development, validation and routine control of a sterilization process for medical devices

ISO 11607-1 Packaging for terminally sterilized medical devices - Part 1: Requirements for materials, sterile barrier systems and packaging systems [Including: Amendment 1 (2014)]

Following testing have been performed:

STUDY	STANDARDS	DESCRIPTION/ CRITERIA	RESULTS
Sterilization Validation - Steam GRAVITY	ANSI/AAMI ST8:2013 ANSI/AAMI ST77:2013 ANSI/AAMI ST79:2017 ANSI/AAMI/ISO 14937:2009/(R)2013	A method of steam Sterilization was validated to a sterility assurance level (SAL) of 10^{-6}	Pass
Sterilant Penetration - Steam GRAVITY	ANSI/AAMI ST8:2013 ANSI/AAMI ST77:2013 ANSI/AAMI ST79:2017	The testing details the methods used in determining the internal temperature profile for wrapped sterilization packs when processed in a steam sterilization gravity cycle at 121^0 C (250°F) for thirty (30) minutes.	Testing has demonstrated adequate sterilant penetration
Validation - Dry Time Study GRAVITY	ANSI/AAMI ST8:2013 ANSI/AAMI ST77:2013 ANSI/AAMI ST79:2017 BS EN 868-8:2009 BS EN 285:2006+A2:2009	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 GRAVITY	ANSI/AAMI ST79:2017 United States Pharmacopeia < 71 >	The study details the methods used in verifying the test samples can maintain the integrity of its contents for an extended period of	No growth

		time following exposure to a steam gravity sterilization process.	
Sterilization Validation - Steam PREVACUUM	ANSI/AAMI ST8:2013 ANSI/AAMI ST77:2013 ANSI/AAMI ST79:2017 ANSI/AAMI/ISO 14937:2009/(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 ST8:2013 ANSI/AAMI ST77:2013 ANSI/AAMI ST79:2017 ANSI/AAMI/ISO 14937:2009/(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 Study PREVACUUM	ANSI/AAMI ST8:2013 ANSI/AAMI ST77:2013 ANSI/AAMI ST79:2017 BS EN 868-8:2009 BS EN 285:2006+A2:2009	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	ANSI/AAMI ST79:2017 United States Pharmacopeia < 71 >	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 process.	No growth
Aerosol Challenge Whole Package Integrity Test - Steam GRAVITY	ANSI/AAMI ST8:2013 ANSI/AAMI ST77:2013 ANSI/AAMI ST79:2017	The testing details the methods used to challenge the effectiveness of the test sample in	The subject wrap, were found to be effective barriers when processed in a Steam Gravity

		maintaining package integrity following a microbial aerosol challenge test.	cycle and subjected to a rigorous microbial aerosol challenge.
Aerosol Challenge Whole Package Integrity Test - Steam PREVACUUM	ANSI/AAMI ST8:2013 ANSI/AAMI ST77:2013 ANSI/AAMI ST79:2017	The testing details the methods used to challenge the effectiveness of the test sample in maintaining package integrity following a microbial aerosol challenge test.	The subject wrap, were found to be effective barriers when processed in a Steam Pre-Vacuum cycle and subjected to a rigorous microbial aerosol challenge.
Bacterial Filtration Efficiency (BFE) of Non-Woven Sterilization Wrap When Processed In a Steam Sterilization Cycle	ASTM F2101-14 EN 14683: 2014 AS4381: 2015	BFE testing is a type of test used to determine the efficiency of filter materials to provide protection against microbial organisms. It	Pass
Physical Integrity	ISO 11607	The purpose of the physical properties testing was to demonstrate passing results for the physical properties for the wrap.	The physical properties testing met the acceptance criteria and demonstrated passing results
Shelf Life Testing	ANSI/AAMI ST8:2013 ANSI/AAMI ST77:2013 ANSI/AAMI ST79:2017	Whole package integrity test of real time shelf life samples	Sterilization Wrap was capable of maintaining sterility and package integrity (when used as a steam sterilization wrapper) following an approximate 18 month period of real time shelf life prior to being sterilized in the steam sterilization cycles

Biocompatibility Assessment

Cytotoxicity testing is a type of biocompatibility test used to determine whether use of a medical device can have any potentially harmful physiological effects. This involves extracting leachable materials from the device or components and analyzing the leachable extracts for potentially harmful chemicals or cytotoxicity. The materials were exposed to one (1) full sterilization cycle.

- ANSI/AAMI/ISO 10993-5 Biological Evaluation of Medical Devices – Part 5: Tests for in vitro Cytotoxicity

Based on the conditions of the study the device was found not to be cytotoxic.

VIII. CONCLUSIONS

The conclusion drawn from the non-clinical tests demonstrate that the subject device (K182565) is as safe, as effective and performs as well as or better than the legally marketed predicated device (K160755).