July 31, 2023

Huaian Seamen Medical Technology Co., LTD
% Liu Hui
General manager
Tianjin Zongxin Weiye Consulting Co, LTD.
Building 3, Jinfeng Building, Nankai District
Tianjin, Tianjin 300110
China

Re: K221767
Trade/Device Name: Surgical Sutures with or without Needle
Regulation Number: 21 CFR 878.5020
Regulation Name: Nonabsorbable Polyamide Surgical Suture
Regulatory Class: Class II
Product Code: GAR, GAW, GAT
Dated: June 14, 2023
Received: June 14, 2023

Dear Liu Hui:

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,

David Krause -S

David Krause, Ph.D.
Deputy Director
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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K221767

Device Name
Surgical Sutures with or without Needle, Polypropylene

Indications for Use *(Describe)*
Non-absorbable Polypropylene Suture is indicated for use in general soft tissue approximation and/or ligation. The device can be left in place for a maximum of 30 days.

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.

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)*
K221767

Device Name
Surgical Sutures with or without Needle, Polyester

Indications for Use *(Describe)*
Non-absorbable Polyester Suture is indicated for use in general soft tissue approximation and/or ligation. The device can be left in place for a maximum of 30 days.

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

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Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

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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)*
K221767

Device Name
Surgical Sutures with or without Needle, Polyamide

Indications for Use *(Describe)*
Non-absorbable Polyamide Suture is indicated for use in general soft tissue approximation and/or ligation. The device can be left in place for a maximum of 30 days.

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)

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Tab # 6 510(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:

1. Date of Preparation: 2023.07.19

2. Sponsor Identification

Huaian Seamen Medical Technology Co.LTD

No. 6, Wang Yuan Pioneering Park (Qunli Road), Yanhe Sub-district Office, Qingjiangpu District, Huai 'an City, Jiangsu Province, China

Establishment Registration Number: 3021275641

Contact Person: Zhang Xinjie

Position: Technical manager

Tel: 13163746779

Email: lifeseasea123@163.com

3. Designated Submission Correspondent

(Primary Contact Person) Hui Liu

(Alternative Contact Person) Anna Sun

Tianjin Zongxin Weiye Consulting Co., Ltd.

Building 3, Jinfeng Building, northeast of the intersection of Nanma Road and Chengxiang West Road, Nankai District, Tianjin City, China

Tel:15922145259

Email: registration_anna@hotmail.com

4. Identification of Proposed Device

Device Trade/Proprietary Name: Surgical Sutures with or without Needle

Classification Information

a. Non-absorbable Polypropylene Suture

(1) Classification Name: Suture, Non-absorbable, Synthetic, Polypropylene
(2) Product Code: GAW
(3) Regulation Number: 878.5010
(4) Class: II
(5) Review Panel: General & Plastic Surgery

b. Non-absorbable Polyester Suture
(1) Classification Name: Suture, Non-absorbable, Synthetic, Polyester
(2) Product Code: GAT
(3) Regulation Number: 878.5000
(4) Class: II
(5) Review Panel: General & Plastic Surgery

c. Non-absorbable Polyamide Suture
(1) Classification Name: Suture, Non-absorbable, Synthetic, Polyamide
(2) Product Code: GAR
(3) Regulation Number: 878.5020
(4) Class: II
(5) Review Panel: General & Plastic Surgery

Indications for Use

a. Non-absorbable Polypropylene Suture is indicated for use in general soft tissue approximation and/or ligation. The device can be left in place for a maximum of 30 days.

b. Non-absorbable Polyester Suture is indicated for use in general soft tissue approximation and/or ligation. The device can be left in place for a maximum of 30 days.

c. Non-absorbable Polyamide suture is indicated for use in general soft tissue approximation and/or ligation. The device can be left in place for a maximum of 30 days.

Device Description

a. The applicant devices of Non-absorbable Polypropylene Suture consist of polypropylene surgical suture made of polypropylene and a stainless steel needle. It is monofilament. It is EO sterilized, and prygon-free. It is dyed by §74.3045 [Phthalocyaninato(2-)] copper.(CI Number 74160) which is less than 0.1 % by weight.
The applicant devices of Non-absorbable Polypropylene Suture are available in 11-0, 10-0, 9-0, 8 -0, 7-0, 6-0, 5-0, 4-0, 3-0, 2-0, 0, 1, 2 and 3, which are the sizes identified in the currently recognized United States Pharmacopoeia.
-

b. The applicant devices of Non-absorbable Polyester Suture consist of a polyester surgical suture made of polyester and a stainless steel needle. It is braided and coated with silicone. It is EO sterilized, and prygon-free.It is undyed (natural white) or dyed green with § 74.3206 D&C Green No. 6. (CI Number 61565), which is less than 0.1 % by weight.
The applicant devices of Non-absorbable Polyester Suture are available in 9-0, 8-0, -0, 6-0, 5-0, 4-0, 3-0, 2-0, 0, 1, 2 and 3, which are the sizes identified in the currently recognized United States Pharmacopoeia.

c. The applicant devices of Non-absorbable Polyamide suture consist of a polyamide surgical suture made of long-chain, aliphatic polymers nylon and a stainless steel needle. It is monofilament. It is EO sterilized, and prygon-free. It is dyed by § 74.3102 FD&C Blue No. 2. (CI Number 73015) or § 73.1410 Logwood Black (CI Number 75290), which is less than 0.1 % by weight.
The applicant devices of Non-absorbable Polyamide suture are available in 11-0, 10-0, 9-0, 8-0, 7-0, 6-0, 5-0, 4-0, 3-0, 2-0, 0, 1, 2 and 3, which are the sizes identified in the currently recognized United States Pharmacopoeia.

The proposed devices are provided sterile and single use.

The proposed device is composed of suture with or without the needle.

The needle is made of stainless steel. The needles are available in six types: Taper, Cutting, Taper Cutting, Reverse Cutting, Diamond, Premium Cutting and Spatula. The Arc (Circle) of needle has 1/4 circle, 3/8circle,1/2circle,5/8circle,compound curve, straight.

The proposed devices are provided in various combinations of suture length, diameter, color (dyed or undyed), quantity of needle and needle types.

The proposed devices are sterilized by EO to achieve a SAL 10^{-6} and supplied in sterility maintenance package which could maintain the sterility of the device during the shelf life of 5 years.

5. Identification of Predicate

Devices Predicate Device
510(k) Number: K080684
Product Name: WG-SURGICAL SUTURES WITH NEEDLE
Manufacturer: Foosin Medical Supplies Inc., 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:

- USP 43-NF 38:2020 Non-absorbable Surgical Suture
- USP 43-NF 38:2020 <85> Bacterial Endotoxins Limit;
- USP 43-NF 38:2020 <71> Sterility Test
- USP 43-NF 38:2020 <861> Sutures - Diameter
- USP 43-NF 38:2020 <871> Sutures - Needle Attachment
- USP 43-NF 38:2020 <881> Tensile Strength
- ISO 10993-3:2014 Biological Evaluation of Medical Devices, Part 3: Tests for Genotoxicity, Carcinogenicity and Reproductive Toxicity;
- ISO 10993-4:2017 Biological evaluation of medical devices--Part 4: Selection of tests for interactions with blood
- ISO 10993-5:2009 Biological evaluation of medical devices -- Part 5: Tests for in vitro cytotoxicity;
- ISO 10993-6:2016 Biological evaluation of medical devices -- Part 6: Tests for local effects after implantation;
- ISO 10993-10: 2010 Biological evaluation of medical devices -- Part 10: Tests for irritation and skin sensitization;
- ISO 10993-11:2017 Biological evaluation of medical devices -- Part 11: Tests for systemic toxicity;
- ISO 11135:2014 Sterilization of health-care products - Ethylene oxide - Requirements for the development, validation and routine control of a sterilization process for medical devices [Including: Amendment 1 (2018)]
- ASTM F88/F88M-15: Standard Test Method for Seal Strength of Flexible Barrier Materials
- ASTM F1929-15 Standard Test Method for Detecting Seal Leaks in Porous Medical Package by Dye Penetration;
- ASTM F1140-13 Standard Test Methods for Internal Pressurization Failure Resistance of Unrestrained Packages

The following stability testing was performed to support the proposed shelf life:
Performance and Package Integrity Test Report after Accelerated Aging (five years)

7. Clinical Test Conclusion

No clinical study is included in this submission.

8. Substantially Equivalent (SE) Comparison

Table 1 Comparison of Technology Characteristics

Item	**Proposed Device** Non-absorbable Polypropylene Suture Non-absorbable Polyester Suture Non-absorbable Polyamide suture	**Predicate Device** K080684 Non-absorbable Polypropylene Suture with Needle Non-absorbable Polyester Suture with Needle Non-absorbable Polyamide Suture with Needle	**Remark**
Product Code	GAW GAT GAR	GAW GAT GAR	SE
Regulation Number	CFR 878. 5010 CFR878.5000 CFR878.5020	CFR 878. 5010 CFR878.5000 CFR878.5020	SE
Class	II	II	SE
Indications for Use	Non-absorbable Polypropylene Suture is indicated for use in general soft tissue approximation and/or ligation. The device can be left in place for a maximum of 30 days. Non-absorbable Polyester Suture is indicated for use in general soft tissue approximation and/or ligation. The device can be left in place for a maximum of 30 days. Non-absorbable Polyamide suture is indicated for use in general soft tissue approximation and/or ligation. The device can be left in place for a maximum of 30 days.	Non-absorbable Polyprolene Suture with Needle is indicated for use in general soft tissue approximation and/or ligation including use in cardiovascular, ophthalmic and neurological procedures. Non-absorbable Polyester Suture with Needle is indicated for use in general soft tissue approximation and/or ligation including use in cardiovascular, ophthalmic and neurological procedures. Non-absorbable Polyamide suture with needle is indicated for use in general soft tissue approximation and/or ligation, including use in ophthalmic procedures.	Different Analysis 1
Configuration	Suture with or without Needle	Suture with or without Needle	SE
Sterility	EO Sterilized	EO Sterilized	SE

SAL	1.0×10^{-6}	1.0×10^{-6}	SE
Single Use	Yes	Yes	SE
Duration of use	Prolonged exposure(24h-30d)	long-term exposure(≥30days)	Different Analysis 2
Material	Polypropylene/ Polyester/Polyamide	Polypropylene/ Polyester/Polyamide	SE
Color	Polypropylene: § 74.3045 [Phthalocyaninato(2-)] copper. (CI Number 74160) Polyester: undyed (natural white) and dyed green with § 74.3206 D&C Green No. 6. (CI Number 61565). Polyamide: § 74.3102 FD&C Blue No. 2.(CI Number 73015) § 73.1410 Logwood Black (CI Number 75290) Weight percentage of color additive is less than 0.1%.	/	Different Analysis 3
Absorbable / Non-absorbable	Non-absorbable	Non-absorbable	SE
Braided / Monofilament	Polyester: braided. Polypropylene/Polyamide: monofilament	Polyester: braided. Polypropylene/Polyamide: monofilament	SE
Suture Size	Polypropylene: 11-0, 10-0, 9-0, 8-0, 7-0, 6-0, 5-0, 4-0, 3-0, 2-0, 0, 1, 2 and 3 Polyester: 9-0, 8-0, 7-0, 6-0, 5-0, 4-0, 3-0, 2-0, 0, 1, 2 and 3 Polyamide: 11-0, 10-0, 9-0, 8-0, 7-0, 6-0, 5-0, 4-0, 3-0, 2-0, 0, 1, 2 and 3	11-0, 10-0, 9-0, 8-0, 7-0, 6-0, 5-0, 4-0, 3-0, 2-0, 0, 1, 2 and 3	Different Analysis 4

Suture Length	Polypropylene: 5cm, 10cm, 13cm, 15cm, 20cm, 23cm, 25cm, 30cm, 45cm, 50cm, 60cm, 70cm, 75cm, 80cm, 85cm, 90cm, 100cm, 120cm, 150cm, 180cm, 200cm, 203cm, 220cm, 240cm, 250cm, 280cm, 300cm, 320cm, 350cm, 390cm Polyester：5cm, 15cm, 23cm, 25cm, 30cm, 45cm, 50cm, 60cm,70cm, 75cm, 90cm, 95cm, 100cm, 107cm, 120cm, 150cm, 180cm, 200cm, 220cm, 250cm, 280cm, 300cm, 320cm, 350cm, 360cm Polyamide：5cm, 10cm, 13cm, 15cm, 18cm, 20cm, 23cm, 25cm, 30cm, 35cm, 38cm, 40cm, 45cm, 50cm, 60cm, 70cm, 75cm, 90cm, 100cm, 120cm, 150cm, 180cm, 200cm, 203cm, 220cm, 240cm, 250cm, 280cm, 350cm	≤3.9m	Different Analysis 5
Diameter of Suture	The suture diameters of proposed device comply with the diameter requirement listed in USP <861>Diameter.	The suture diameters of proposed device comply with the diameter requirement listed in USP <861> Diameter.	SE
Tensile Strength	The tensile strengths of proposed device comply with the tensile requirement listed in USP <881> Tensile Strength	The tensile strengths of proposed device complies with the tensile requirement listed in USP <881> Tensile Strength<881> Tensile Strength	SE
Needle Attachment	The bond between suture and needle of the applicant device meet the requirements defined in USP <871>.	The bond between suture and needle of the applicant device meet the requirements defined in USP <871>.	SE
Biocompatibility of Needles			

Cytotoxicity	No cytotoxicity.	The specific test items are unknown. However, the product should meet the requirements of ISO10993 series standards.	Different Analysis 6
Max Sensitization	No skin sensitization.		
Intracutaneous Reactivity Test	No intracutaneous reactivity.		
Acute systemic toxicity	No systemic toxicity.		
Pyrogenicity test	No potential febrile reaction.		
Hemolysis test (Direct contact)	No Hemolysis		
Hemolysis test (Indirect contact)	No Hemolysis		
Biocompatibility of Sutures			
Cytotoxicity	No cytotoxicity.	The specific test items are unknown. However, the product should meet the requirements of ISO10993 series standards.	Different Analysis 7
Max Sensitization	No skin sensitization.		
Intracutaneous Reactivity Test	No intracutaneous reactivity.		
Acute Systemic Toxicity Test	No systemic toxicity.		
Genotoxicity	No genotoxicity.		
Pyrogenicity	No potential febrile reaction.		
Muscle Implantation Study	No reaction to the tissue.		
Subacute/Subchronic Toxicity Study	No systemic toxicity.		
Hemolysis Test (Direct Contact)	No Hemolysis		
Hemolysis Test (Indirect Contact)	No Hemolysis		

Different Analysis 1- Indications for Use

The Indications for Use of proposed device is different from the predicate device. However, the Indications for Use of the proposed device is included in the range of the Indications for Use of the predicate device.
Therefore, this difference does not affect safety and effectiveness of the proposed device.

Different Analysis 2- Duration of use

The Duration of use of proposed device is different from the predicate device. However, the Duration of use of the proposed device is included in the range of the Duration of use of the predicate device.
Therefore, this difference does not affect safety and effectiveness of the proposed device.

Different Analysis 3- Color

The color of predicate devices are not known. The color additive is usually used for Non-Absorbable Surgical Suture. The proposed device has been demonstrated to comply the requirements listed in USP Monograph of Non-Absorbable Surgical Suture. The color additive used conform to requirement of § 70.5 General restrictions on use of color additives- (c) Color additives for use in surgical sutures. Therefore, this item does not impact the safety and effectiveness.

Different Analysis 4- Suture Size

The Suture Size of the proposed device is within the scope of the Suture Size of predicate devices. The proposed device has been demonstrated to comply the requirements listed in USP Monograph of Non-Absorbable Surgical Suture. Therefore, this item does not impact the safety and effectiveness.

Different Analysis 5- Suture Length

The Suture Length of the proposed device is within the scope of the Suture length of predicate devices. The proposed device has been demonstrated to comply the requirements listed in USP Monograph of Non-Absorbable Surgical Suture. Therefore, this item does not impact the safety and effectiveness.

Different Analysis 6- Needle Biocompatibility

The needle biocompatibility of Proposed Device and Predicate Device should meet the requirements of ISO10993 series standards; although we do not know the specific test items of Predicate Device, but the needle biocompatibility tests of Proposed Device have been performed in Cytotoxicity Test Report, Max Sensitization Test Report, Intracutaneous Reactivity Test Report, Acute Systemic Toxicity Test Report, Pyrogenicity Test Report, Hemolysis Test Report (Direct contact), Hemolysis Test Report (Indirect contact). These studies can demonstrate the needle biocompatibility of Proposed Device. Therefore, this item is considered to be substantially equivalent.

Different Analysis 7- Suture Biocompatibility

The biocompatibility of Proposed Device and Predicate Device should meet the requirements of ISO10993 series standards; although we do not know the specific test items of Predicate Device, but the biocompatibility tests of Proposed Device have been performed in Cytotoxicity, Max Sensitization, Intracutaneous Reactivity Test, Acute Systemic Toxicity Test, Genotoxicity, Pyrogenicity, Muscle Implantation Study, Subacute/Subchronic Toxicity Study, Hemolysis Test (Direct Contact) and Hemolysis Test (Indirect Contact). These studies can demonstrate the biocompatibility of Proposed Device. Therefore, this item is considered to be substantially equivalent.

9. Substantially Equivalent (SE) Conclusion

Based on the comparison and analysis above, the proposed devices are determined to be Substantially Equivalent (SE) to the predicate device.