August 25, 2023

Shandong Haidike Medical Products Co.,Ltd.
Yan Wang
Registration Manager
Tianfu Road, Dongcheng District, Shan County
Heze, Shandong 274300
China

Re: K231183
Trade/Device Name: Non absorbable Surgical Polyester Suture
Regulation Number: 21 CFR 878.5000
Regulation Name: Nonabsorbable Poly(Ethylene Terephthalate) Surgical Suture
Regulatory Class: Class II
Product Code: GAT
Dated: July 25, 2023
Received: July 25, 2023

Dear Yan 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,

Tek N. Lamichhane -S

Digitally signed by Tek N. Lamichhane -S
Date: 2023.08.25 10:53:57 -04'00'

Tek N. Lamichhane, Ph.D.
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

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)*
K231183

Device Name
Non-absorbable Surgical Polyester Suture

Indications for Use *(Describe)*
Non-absorbable Surgical Polyester Suture is indicated for use in general soft tissue approximation and/or ligation, but not for use in ophthalmic, cardiovascular, and neurological procedures. The device is limited to use where short term wound support (7-10 days) is required and can be left in place for a maximum of 10 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:

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

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) Summary-K231183

This 510(k) Summary is being submitted in accordance with requirements of Title 21, CFR Section 807.92.

1. Administrative Information

Date of preparation: 07/24/2023

Shandong Haidike Medical Product Co., Ltd.
Tianfu Road, Dongcheng District, Shan County, 274300 Heze City, Shandong Province, China.

Establishment Registration Number: 3016426842

Contact Person: Yan Wang
Position: Registration Manager
Tel: +86-530-4660062
Fax: +86-530-4660055
Email: registration01@suturescn.com

2. Identification of Subject Device

Trade Name: Non-absorbable Surgical Polyester Suture
Common Name: Nonabsorbable Poly (Ethylene Terephthalate) Suture

Regulatory Information

Classification Name: Suture, Nonabsorbable, Synthetic, Polyester
Classification: II
Product Code: GAT
Regulation Number: 21CFR 878.5000
Review Panel: General & Plastic Surgery

3. Identification of Predicate Device

510(k) Number: K172149
Regulation Number: 21CFR 878.5000
Classification: II
Product Code: GAT
Review Panel: General & Plastic Surgery
Product name: MERICRON XL - Non-Absorbable Polyester Surgical Suture

4. Device Description

The subject device is a coated, braided, non-absorbable synthetic surgical suture composed of polyethylene terephthalate which is supplied sterile. The suture is coated with bees wax and dyed green. The color additive is D&C Green 6.

The subject device will be offered in diameters ranging from USP size 6-0 through 2 and available in length varying from 45cm to 150cm with or without needles attached.

5. Indications for Use:

Non-absorbable Surgical Polyester Suture is indicated for use in general soft tissue approximation and/or ligation, but not for use in ophthalmic, cardiovascular, and neurological procedures. The device is limited to use where short term wound support (7-10 days) is required and can be left in place for a maximum of 10 days.

6. Summary of Technological Characteristics

Table 1: Comparison of Technological Characteristics

ITEM	Subject Device (K231183)	Predicate Device K172149	Remark
Product Code	GAT	GAT	Same
Regulation Number	21CFR 878.5000	21CFR 878.5000	Same
Class	II	II	Same
Sterile	Ethylene Oxide (EO)	Ethylene Oxide (EO)	Same
Indication for Use	Non absorbable Surgical Polyester Suture is indicated for use in general soft tissue approximation and/or ligation, but not for use in ophthalmic, cardiovascular, and neurological procedures. The device is limited to use where short term wound support (7-10 days) is required and can be left in place for a maximum of 10 days.	MERICRON XL suture is intended for use in general soft tissue approximation and/or ligation including cardiovascular surgery, neurosurgery, and ophthalmic procedures.	Analysis 1
Configuration	Polyester Suture with or without needle	1、MERICRON XL™ Suture with or without needle. 2、MERICRON XL™ Suture is available with or without PTFE (Polytetrafluoroethylene) Pledget	Analysis 2
Suture			
Material	polyethylene terephthalate	poly (ethylene terephthalate)	Same
Structure	braided	braided	Same
Coating	Bees wax	Bees wax	Same
Dyed, Un-dyed	Dyed	Undyed/Dyed	Same

Colorant	D&C Green 6	D & C Green No.6	same
Length	45cm to 150cm	Unknown	Analysis 3
Diameter	6-0 through 2	6-0 through 5	
Needle			
Material	Stainless Steel	Stainless Steel	Same
Performance Test			
Diameter of suture	Comply with USP <861>	All characteristics meet USP Requirement	Same
Needle Attachment	Comply with USP <871>		
Tensile Strength	Comply with USP <881>		
Length	Not less than 95.0% of the length stated on the label	Unknown	Analysis 3
Biocompatibility			
Cytotoxicity (ISO 10993-5)	Pass	The Surgical Suture has been Evaluated: a.In Vitro Cytotoxicity Study b. Skin Sensitization Study c.Intracutaneous Reactivity Test d.Acute Systemic Toxicity Study e.Sub Chronic Toxicity Study f. Intramuscular Implantation Test g. Bacterial Reverse Mutation Test h. Mammalian Erythrocyte Micronucleus Test i. In Vitro Hemolysis Test j. Pyrogen Test	Analysis 4
Sensitization (ISO 10993- 10)	Pass		
Intracutaneous Reactivity (ISO 10993- 10)	Pass		
Acute systemic toxicity (ISO 10993- 11)	Pass		
Pyrogen (USP 43 NF38 <151>)	Pass		
Subacute Systemic Toxicity (ISO 10993- 11)	Pass		
Bacterial Reverse Mutation (ISO 10993-3)	Pass		
Chromosome Aberration (ISO 10993-3)	Pass		
Gene Mutation (ISO 10993-3)	Pass		
Implantation (ISO 10993-6)	Pass		
Hemolysis (ASTM F756-17)	Pass		

Analysis 1-Indications for Use

The indications for use for the subject device is not exactly the same as the predicate device. The subject device is indicated for general tissue approximation but not for use in ophthalmic, cardiovascular, and neurological procedures. In addition, the longest duration of use for the subject device is up to 10 days,

while the predicate device is a permanent contact device per the contact duration. However, the biocompatibility tests have been conducted on the subject device, and the test results showed that the material and colorant of the subject device will not have any adverse effects when used for up to 10 days.

Analysis 2-Configuration

The configuration of the subject device is different from the predicate device. However, the configuration of Polyester Suture with or without a needle is the same as the predicate device.

Analysis 3-Length & Diameter

The length and diameter of the subject device is different from the predicate device. However, the length and diameter of the proposed device is within the range of that of the predicate device. In addition, the performance test about the length and diameter has been conducted on the subject device and the test result shows that the length and diameter of the subject device met the acceptance criteria. Therefore, the difference will not affect the safety and effectiveness of the subject device.

Analysis 4-Biocompatibility

The subject device is a prolonged contact device, while the predicate device is a permanent contact device. Based on the identified contact duration and indication for use of subject device, the biocompatibility tests were performed in accordance with ISO 10993- 1: 2018 Biological evaluation of medical devices -- Part 1: Evaluation and testing within a risk management process, and FDA guidance document entitled Use of International Standard ISO-10993, "Biological Evaluation of Medical Devices Part 1: Evaluation and Testing" dated September 4, 2020.
Although the Biocompatibility contact duration is not the same, the biocompatibility test has been conducted on the subject device and the test result showed that the material of the subject device will not have adverse effects.

7. Performance Data

a. Non-clinical Testing

The biocompatibility evaluation for the subject device was conducted in accordance with the ISO 10993-1:2018 "Biological Evaluation of Medical Devices - Part 1: Evaluation and Testing Within a Risk Management Process".

The tests were conducted following these standards:

- ISO 10993-3:2014 Biological evaluation of medical devices - Part 3: Tests for genotoxicity, carcinogenicity and reproductive toxicity
- 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 10993-7:2008 Biological evaluation of medical devices - Part 7: Ethylene oxide sterilization residuals
- ISO 10993-10 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

- USP<151> Pyrogen Test (USP Rabbit Test)
- ASTM F756-17 Standard Practice for Assessment of Hemolytic Properties of Materials

Non-clinical tests were conducted to verify that the subject device met all design specifications as was Substantially Equivalent (SE) to the subject device. The test results demonstrated that the subject device complies with the following standards:

- 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 Packaging by Dye Penetration
- USP<85>Bacterial Endotoxins Test
- USP<861>Sutures - Diameter
- USP<871>Sutures - Needle Attachment
- USP<881>Tensile Strength

c. Animal Study

No animal study is included in this submission.

d. Clinical Test Conclusion

No clinical study is included in this submission.

7. Conclusion

The conclusions drawn from the non-clinical tests demonstrate that the subject device, Non-absorbable Surgical Polyester Suture (K231183), is as safe, as effective, and performs as well as the legally marketed predicate device, K172149.