January 16, 2024

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

Re: K232355
Trade/Device Name: Non absorbable Surgical Silk Suture
Regulation Number: 21 CFR 878.5030
Regulation Name: Natural Nonabsorbable Silk Surgical Suture
Regulatory Class: Class II
Product Code: GAP
Dated: December 14, 2023
Received: December 14, 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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device"

(https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

Yu-chieh Chiu -S

for Tek Lamichhane, Ph.D.
Assistant Director
DHT4B: Division of Infection Control
and Plastic and Reconstructive 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)*
K232355

Device Name
Non absorbable Surgical Silk Suture

Indications for Use *(Describe)*
Non absorbable Surgical Silk Suture is indicated for use in general soft tissue approximation and/or ligation, but not for use in ophthalmic procedures, 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.

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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: K232355

1. Date of Preparation: Jan. 12, 2024

2. Sponsor Identification

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

Establishment Registration Number: 3016426842

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3. Identification of Subject Device:

Trade Name: Non absorbable Surgical Silk Suture
Common Name: Natural Non absorbable Silk Surgical Suture

Regulatory Information

Classification Name: Suture, Non absorbable, Silk;
Classification: II;
Product Code: GAP;
Regulation Number: 21CFR 878.5030;
Review Panel: General & Plastic Surgery

4. Identification of Predicate Device

510(k) Number: K161633
Regulation Number: 21CFR 878.5030
Classification: II;
Product Code: GAP;
Review Panel: General & Plastic Surgery;
Product name: REXSIL

5. Device Description

Non absorbable Surgical silk Suture is a nonabsorbable, braided surgical suture which is supplied sterile, surgical suture composed of an organic protein called fibroin. This protein is derived from the domesticated species Bombyx mori of the family Bombycidae. Silk for braided material is processed to remove the natural waxes and gums. Silk suture is dyed black(Logwood extract) and coated with silicone. The quantity of color additive is not to exceed 1.00% by weight of the suture.

The 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. Silk suture meets all the requirements of USP for nonabsorbable surgical suture. The suture needle are made from medical stainless steel, the grade of medical stainless steel is SUS 420 J2.

6. Indications for Use:

Non absorbable Surgical Silk Suture is indicated for use in general soft tissue approximation and/or ligation, but not for use in ophthalmic procedures, 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.

7. Technological characteristic comparision

Table 1 Comparision of Technological Characteristics

ITEM	Proposed Device	Predicate Device K161633
Product Code	GAP	GAP
Regulation Number	21CFR 878.5030	21CFR 878.5030
Class	II	II
Sterile	Ethylene Oxide (EO)	Ethylene Oxide (EO)
Indication for Use	Non absorbable Surgical Silk Suture is indicated for use in general soft tissue approximation and/or ligation, but not for use in ophthalmic procedures, 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.	REXSIL is indicated for use in general soft tissue approximation and/or ligation, including use in ophthalmic procedures, but not for use in cardiovascular or neural tissue.
Configuration	Silk Suture with or without needle	Silk Suture with or without needle
Raw Suture Material	Silk suture	Silk suture
Suture Manufacturer	Ashaway Line & Twine Mfg. Co.	Ashaway Line & Twine Mfg. Co.

Structure	Braided	Braided
Dyed, Un-dyed	Dyed suture Black	Dyed suture Black (Logwood) and Undyed suture (Natural)
Colorant	Black (Logwood extract)	Black (Logwood)
Length	45cm to 150cm	30cm, 35cm, 40cm, 45cm, 50cm, 55cm, 60cm, 70cm, 75cm, 100cm, 110cm, 150cm, 180cm,
Diameter	6-0 through 2	Dyed suture Black (Logwood): USP 8-0 ~USP 2 Undyed suture (Natural): USP 7-0~USP 2
Needle		
Material	Stainless Steel	Stainless Steel
Performance Test		
Diameter of suture	Comply with USP <861>	All characteristics meet USP Requirement
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

The Indications for Use (duration of use) is different between the subject and predicate devices. The proposed device is indicated for use in general soft tissue approximation and/or ligation, but not for use in ophthalmic procedures, cardiovascular and neurological procedures. In addition, the longest duration of use for the proposed device is up to 10 days, while the predicate device is a permanent contact device per the contact duration. However, the biocompatibility test has been conducted in accordance with ISO 10993 per the contact class on the proposed device and the test result showed that the material and colorant of the proposed device will not have any adverse effects when used for up to 10 days.

8. 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:

- 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
- ASTM F756-17 Standard Practice for Assessment of Hemolytic Properties of Materials
- 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 :2010Biological 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)
- USP<85>Bacterial Endotoxins Test
- USP<861>Sutures - Diameter
- USP<871>Sutures - Needle Attachment
- USP<881>Tensile Strength

9. Clinical Test Conclusion

No clinical study is included in this submission.

10. Conclusion

The proposed device, Non absorbable Surgical Silk Suture is determined to be Substantially Equivalent to the predicate devices in respect of safety and performance.