September 14, 2023

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

Re: K230746
Trade/Device Name: Non absorbable Surgical Polypropylene Suture
Regulation Number: 21 CFR 878.5010
Regulation Name: Nonabsorbable Polypropylene Surgical Suture
Regulatory Class: Class II
Product Code: GAW
Dated: March 15, 2023
Received: March 17, 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: 2023.09.14 09:51:31 -04'00'

Tek N. Lamichhane, Ph. D.
Assistant Director
DHT4B: Division of Infection Control
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and Infection Control Devices
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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)*
K230746

Device Name
Non Absorbable Surgical Polypropylene Suture

Indications for Use *(Describe)*
Non absorbable Surgical Polypropylene 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.

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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: K230746

1. Date of Preparation: 08/12/2023

2. Sponsor Identification

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

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3. Identification of Subject Device:

Trade Name: Non Absorbable Surgical Polypropylene Suture
Common Name: Nonabsorbable Polypropylene Surgical Suture

Regulatory Information

Classification Name: Suture, Nonabsorbable, Synthetic, Polypropylene
Classification: II
Product Code: GAW
Regulation Number: 21CFR 878.5010
Review Panel: General & Plastic Surgery

4. Identification of Predicate Device
510(k) Number: K080684
Regulation Number: 21CFR 878.5010
Classification: II
Product Code: GAW
Review Panel: General & Plastic Surgery
Product name: WG-Surgical Sutures with Needle

5. Device description

The subject device is a nonabsorbable monofilament surgical suture which is supplied sterile. The proposed device is dyed blue. The color additive is [phtalocyaninato(2-)] copper(Color Index Number 74160), and the weight percentage for the color additive is less than 0.1%. The device will be offered in diameters ranging from USP size 6-0 through 2 and is available in length 75cm or 150cm with or without needles attached. Polypropylene suture meets all the requirements of USP for Non-absorbable surgical suture.

6. Indications for Use

Non absorbable Surgical Polypropylene 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 comparison

Table 1: Comparison of Technological Characteristics

ITEM	Subject Device (K230746)	Predicate Device (K080684)	Remark
Product Code	GAW	GAW	Same
Regulation Number	21CFR 878.5010	21CFR 878.5010	Same
Class	II	II	Same
Sterile	Ethylene Oxide（EO）	Ethylene Oxide（EO）	Same
Indication for Use	Non absorbable Surgical Polypropylene 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.	Nonabsorbable Polypropylene Suture with Needle is indicated for use in general soft tissue approximation and/or ligation including use in cardiovascular, ophthalmic and neurological procedures.	Analysis 1
Configuration	Polypropylene Suture with or without needle	Polypropylene Suture with needle	Similar
Suture			
Material	Polypropylene	Polypropylene	Same

Structure	Monofilament	Monofilament	Same
Dyed, Un-dyed	Dyed	Dyed	Same
Colorant	[phtalocyaninato(2-)] copper	Blue	Analysis 2
Length	75cm，150cm	Unknown	Analysis 3
Diameter	6-0 through 2	10-0 through 2	
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	Analysis3
Suture Biocompatibility			
Cytotoxicity	The viability is not reduced to less than 70%	The specific test items are unknown. However, the product should meet the requirements of ISO10993 series standards.	
Sensitization	The Magnusson and Kligman grades is less than 1.		
Intracutaneous Reactivity	The erythema and edema grades is less than 1.0.		
Acute systemic toxicity	No animal died or abnormal behavior occurred.		
Pyrogen	Temperature raise is less than 0.5℃		
Subacute Systemic Toxicity	No behavioral change or sign of toxicity was observed. Clinical pathology parameter within the reference range. No macroscopic changes in the viscera at necropsy. Histopathology within normal histomorphological limits		
Bacterial Reverse Mutation	No obviously increase in the mean number of revertant of colonies between the test group and control group.		
Chromosome Aberration	No significant difference in the percentage of cells with chromosome aberrations between the test group and control group.		
Gene Mutation	There was no significant difference in the TFT-resistant mutant frequency between the test article and the negative control		

Implantation	No lesion at the implantation site. The irritation score is less than 1.0.		
Hemolysis	Hemolytic index is less than 2%		

Analysis 1-Indication for Use

The indication for use for the subject device is not exactly the same as the predicate device. The proposed device is just indicated for general tissue approximation but not for use in ophthalmic procedures, cardiovascular and neurological procedures and this indication can be covered by the predicate device. 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 on the proposed device and the test result showed that the material and colorant of the proposed device will not have an adverse effect when used for up to 10 days.

Analysis 2- Colorant

The material and colorant of the proposed device is different from the predicate device. However, the biocompatibility test has been conducted on the proposed device and the test result showed that the material and colorant of the proposed device will not have adverse effects. Therefore, the difference will not affect the safety and effectiveness of the proposed device.

Analysis 3- Length & Diameter

The length and diameter of the proposed device is different from the predicate device. However, the length and diameter of the proposed device are 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 proposed device met the acceptance criteria. Therefore, the difference will not affect the safety and effectiveness of the proposed device.

8. Non-Clinical Performance Data

Non clinical tests were conducted to verify that the subject device met all design specifications as was Substantially Equivalent (SE) to the predicate 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
- 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 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)
- USP<85>Bacterial Endotoxins Test
- USP<861>Sutures - Diameter
- USP<871>Sutures - Needle Attachment
- USP<881>Tensile Strength
- ASTM F3014-14 Standard Test Method for Penetration Testing of Needles Used in Surgical Sutures
- ASTM F1874-98 Standard Test Method for Bend Testing of Needles Used in Surgical Sutures

9. Clinical Test Conclusion

No clinical study is included in this submission.

10. Conclusion

The conclusions drawn from the nonclinical tests demonstrate that the proposed subject device is as safe, effective, and performs as well as the legally marketed predicate device, K080684.