December 22, 2021

Shandong Haidike Medical Product Co., Ltd.
% Diana Hong
General Manager
Mid-Link Consulting Co., Ltd
P.O. Box 120-119
Shanghai, 200120
China

Re: K212603
Trade/Device Name: Non Absorbable Surgical Nylon Suture
Regulation Number: 21 CFR 878.5020
Regulation Name: Nonabsorbable Polyamide Surgical Suture
Regulatory Class: Class II
Product Code: GAR
Dated: November 17, 2021
Received: November 18, 2021

Dear Diana Hong:

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,

Deborah Fellhauer, RN, BSN
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)*
K212603

Device Name
Non Absorbable Surgical Nylon Suture

Indications for Use *(Describe)*
Non Absorbable Surgical Nylon Suture is indicated for use in general soft tissue approximation and/or ligation, the device can be left in place for a maximum of 7 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.

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: K212603

1. Date of Preparation: 12/17/2021

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

Contact Person: Lili Xu
Position: Registration Manager
Tel: +86-530-4660062
Fax: +86-530-4660055
Email: registration@suturescn.com

3. Designated Submission Correspondent

Ms. Diana Hong (Primary Contact Person)
Ms. Ying Xu (Alternative Contact Person)

Mid-Link Consulting Co., Ltd
P.O. Box 120-119, Shanghai, 200120, China

Tel: +86-21-22815850
Fax: 360-925-3199
Email: info@mid-link.net

4. Identification of Proposed Device

Trade Name: Non Absorbable Surgical Nylon Suture
Common Name: Nonabsorbable Polyamide Surgical Suture

Regulatory Information

Classification Name: Suture, Nonabsorbable, Synthetic, Polyamide;
Classification: II;
Product Code: GAR;
Regulation Number: 21CFR 878.5020
Review Panel: General & Plastic Surgery;

Indication for Use:
Non Absorbable Surgical Nylon Suture is indicated for use in general soft tissue approximation and/or ligation, the device can be left in place for a maximum of 7 days.

Device Description

The proposed device is a nonabsorbable monofilament surgical suture which is supplied sterile. The proposed 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. The proposed device is dyed blue. The color additive is FD&C BLUE NO. 2, the weight percentage for color additive is less than 0.1%.

5. Identification of Predicate Device

510(k) Number: K151165
Regulation Number: 21 CFR 878.5020
Classification: II
Product Code: GAR
Review Panel: General & Plastic Surgery
Product Name: Dafilon Nonabsorbable Polyamide Surgical Suture

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:

- 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 43-NF38:2020 <151> Pyrogen Test (USP Rabbit Test)
- USP 43-NF38:2020 <85> Bacterial Endotoxins Test
- USP 43-NF38:2020 <881> Tensile Strength
- USP 43-NF38:2020 <861> Sutures - Diameter
- USP 43-NF38:2020 <871> Sutures - Needle Attachment

7. Clinical Test Conclusion

No clinical study is included in this submission.

8. Summary of Technological Characteristics

Table 1 Comparison of Technology Characteristics

ITEM	Proposed Device	Predicate Device K151165	Remark
Product Code	GAR	GAR	Same
Regulation Number	21CFR 878.5020	21CFR 878.5020	Same
Class	II	II	Same
Indication for Use	Non Absorbable Surgical Nylon Suture is indicated for use in general soft tissue approximation and/or ligation, the device can be left in place for a maximum of 7 days.	Dafilon Nonabsorbable Polyamide Surgical Sutures are indicated for use in all types of general soft tissue approximation and/or ligation, including use in cardiovascular, ophthalmic, microsurgery and neurological procedures	Similar
Structure	Monofilament	Monofilament	Same
Length	45cm to 150cm	3cm to 250cm	Different
Diameter	6-0 through 2	11-0 through 5	
Needle	With or without needles attached	With or without needles attached	Same
Duration of use	Up to 7 days	Permanent	Different
Performance Test			
Diameter	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	Different
Material	Polyamide (PA 6/66) Stainless Steel Wires	Polyamide 6 and/or polyamide 6,6 300 or 400 series stainless steel	Different
Dyed, Un-dyed	Dyed	Dyed and Un-dyed	
Colorant	Blue FD&C BLUE NO. 2 Weight percentage less than 0.1%	[Phthalocyaninato(2-)] copper or logwood extract	
Sterile	Ethylene Oxide (EO)	Gamma Irradiation or Ethylene Oxide (EO)	Different
Biocompatibility			
Cytotoxicity	The viability is not reduced to less than 70%	Comply with the requirement of ISO 10993 Implantation (4 week)	Same
Sensitization	The Magnusson and Kligman grades is less than 1.		
Irritation	The erythema and edema grades is less than 1.0		
Implantation	No lesion at the implantation site		

	The irritation score is less than 1.0		
Systemic Toxicity	No animal died or abnormal behavior occurred. The weight loss not exceed 10%	/	
Pyrogen	Temperature raise 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 statistical significance for the number of revertant colonies between the test group and control group. No statistically significant dose-effect relationship was observed		
Gene Mutation	No concentration-related increase of mutant frequency.		
Chromosome Aberration	No significant difference in the percentage of cells with structural aberrations between the test group and control group.		
Hemolysis	Hemolytic index is less than 2%		

Similar-Indication for Use

The indication for use for proposed device is not exactly same as the predicate device. The proposed device is just indicated for general tissue approximation and this indication can be covered by the predicate device. In addition, the longest duration of use for the proposed device is up to 7 days, while it the predicate device is 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 7 days.

Different - 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 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 proposed device and test result shows that the length and diameter of the proposed device met the acceptance criteria.

Different-Duration of Use

The duration of use for the proposed device is different from predicate device. The proposed device is a prolonged contact device, while the predicate device is permanent contact device. Although the duration of use is not same, 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 effect.

Different - Material & 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 effect.

Different - Sterile

The sterilization method of the proposed device is different from the predicate device. However, the EO sterilization method is also used by the predicate device.

9. Substantially Equivalent (SE) Conclusion

The conclusions drawn from the nonclinical tests demonstrate that the proposed subject device is as safe, as effective, and performs as well as the legally marketed predicate device K151165.