March 2, 2020

Yunyi (Beijing) Medical Device Co., LTD
℅ Diana Hong
General Manager
Mid-Link Consulting Co. Ltd
P.O Box 120-119
Shanghai, 200120 Cn

Re: K192637
Trade/Device Name: High Strength Suture
Regulation Number: 21 CFR 878.5000
Regulation Name: Nonabsorbable Poly(Ethylene Terephthalate) Surgical Suture
Regulatory Class: Class II
Product Code: GAT
Dated: September 20, 2019
Received: September 24, 2019

Dear Ms. 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,

For Cindy Chowdhury, Ph.D., M.B.A.
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K192637

Device Name
High Strength Suture

Indications for Use *(Describe)*
The device is indicated for use in general soft tissue approximation and/or ligation, including use in allograft tissues for orthopedic procedures

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.

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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: K192637

1. Date of Preparation: 08/06/2019

2. Sponsor Identification

Yunyi (Beijing) Medical Device Co., LTD.
Floor 1-4, Building 4, No. 9 Tianfu Street, Biomedical Base, Daxing District, Beijing 102600, People's Republic of China

Establishment Registration Number: Not registered

Contact Person: Xiaowei Liu
Position: General Manager
Tel: +86-10-57234533
Fax: +86-10-57234533
Email:liuxiaowei@yunyimedical.com

3. Designated Submission Correspondent

Ms. Diana Hong (Primary Contact Person)
Mr. 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: High Strength Suture
Common Name: Polyblend Suture, Non-absorbable Surgical Sutures
Size：UP-(2-0) W, UP-0W, UP-2W, UP-5W and UP-7W

Regulatory Information

Classification Name: Nonabsorbable Poly (Ethylene Terephthalate) Surgical;
Classification: II;
Product Code: GAT;
Regulation Number: 21 CRFR878.5000
Review Panel: General& Plastic Surgery;

Indication for Use:

The device is indicated for use in general soft tissue approximation and/or ligation, including use in allograft tissues for orthopedic procedures.

Device Description

The proposed device is a braided synthetic, non-absorbable surgical suture made of ultra-high molecular weight polyethylene and medical adhesive at both ends of the suture. The proposed device is undyed and uncoated. The sutures are available in a range of sizes. The device does not contain needle. And the device is provided in sterile.

5. Identification of Predicate Device

510(k) Number: K190817
Product Name: HS Fiber® Suture
Manufacturer: Riverpoint Medical

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 41-NF 36:2018 Non-absorbable Surgical Suture
- USP 41-NF 36:2018 <881> Tensile Strength

- USP 41-NF 36:2018 <861> Sutures – Diameter
- 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
- ISO 10993-5:2009 Biological Evaluation Of Medical Devices - Part 5: Tests For In Vitro Cytotoxicity
- ISO 10993-10:2010 Biological Evaluation Of Medical Devices - Part 10: Tests For Irritation And Skin Sensitization
- ISO 10993-7:2008 Biological Evaluation Of Medical Devices - Part 7: Ethylene Oxide Sterilization Residuals
- ISO 10993-11:2017 Biological Evaluation Of Medical Devices - Part 11: Tests For Systemic Toxicity
- USP 41 NF 36 <151> Pyrogen Test (USP Rabbit Test)
- ISO 10993-3:2014 Biological Evaluation Of Medical Devices - Part 11: Tests For Systemic Toxicity
- ISO 10993-6:2016 Biological Evaluation Of Medical Devices -- Part 6: Tests For Local Effects After Implantation
- USP 41 NF 36 <85> Bacterial Endotoxins Test

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	Predicate Device K190817
Product Code	GAT	GAT
Regulation Number	21 CRFR878.5000	21 CRFR878.5000
Indication for Use	The device is indicated for use in general soft tissue approximation and/or ligation, including use in allograft tissues for orthopedic procedures.	HS Fiber sutures are indicated for use in general soft tissue approximation and/or ligation, including use in cardiovascular surgery, and the use of allograft tissues for orthopedic procedures.
Material	ultra-high molecular weight polyethylene	ultra-high molecular weight polyethylene
Color	Undyed	Dyeing
Absorbable / Non-absorbable	Non-absorbable	Non-absorbable
Braided / Monofilament	Braided	Braided
Sterile	EO Sterilized	Unknown
Suture Size	UP-(2-0) W, UP-0W, UP-2W, UP-5W ,UP-7W	Unknown
Single Use	Yes	Yes
Performance	Comply with: USP 41 <861> USP 41 <881>	Comply with: USP <861> USP <881>
Biocompatibility		
Cytotoxicity	No cytotoxicity	Comply with ISO 10993
Intracutaneous Study	No irritation	
Sensitization	No sensitization	
Pyrogenicity Test	No pyrogenicity	
Acute Systemic Toxicity	No systemic toxicity	
Bacterial Reverse Mutation	Not induce backward mutation	
Gene Mutation Test	Non-mutagenic	
Muscle Implantation Test	Non-irritant to the muscle tissue	
Subchronic Toxicity Test	No subchronic toxicity	

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 devices.