January 8, 2020

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

Re: K202291
Trade/Device Name: Button Loop
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth Or Threaded Metallic Bone Fixation Fastener
Regulatory Class: Class II
Product Code: MBI
Dated: December 16, 2020
Received: December 18, 2020

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,

Laura C. Rose, Ph.D.
Assistant Director
DHT6C: Division of Restorative, Repair,
and Trauma Devices
OHT6: Office of Orthopedic 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)*

Device Name
Button Loop

Indications for Use *(Describe)*
The Button Loop is used for the fixation of soft tissue to bone in orthopedic procedures such as ACL repair.

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: K202291

1. Date of Preparation: 12/16/2020

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

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3. Designated Submission Correspondent

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

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4. Identification of Proposed Device

Trade Name: Button Loop
Common Name: Fastener, Fixation, Soft Tissue

Regulatory Information

Classification Name: fastener, fixation, nondegradable, soft tissue
Classification: II;
Product Code: MBI
Regulation Number: 21 CFR Part 888.3040
Review Panel: Orthopedic

Indication for Use Statement:

The Button Loop is used for the fixation of soft tissue to bone in orthopedic procedures such as ACL repair.

Device Description

The proposed device, Button Loop is a machined titanium implant designed to provide fixation in the repair of tendons and ligaments. It consists of a titanium implantable button with a pre-attached loop. This implantable loop has non-absorbable suture attached to the button for assisting in the button placement and is discarded after the device placement. The button is offered in 12mm one size and loop is available in size ranges of 10~60mm in 5mm increments to accommodate different graft sizes.

5. Identification of Predicate Device

510(k) Number: K130814
Product Name: RIGIDLOOP Cortical Fixation System

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:

- 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: 2010 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 <85> Bacterial Endotoxins Test
- ASTM F1929-15 Standard Test Method for Detecting Seal Leaks in Porous Medical Packaging by Dye Penetration
- ASTM F88/88M-15 Standard Test Method for Seal Strength of Flexible Barrier Materials

Mechanical test has been conducted on the proposed device and predicate device to evaluate its mechanical strength. The mechanical test include fatigue test and static test. The fatigue test evaluate the maximum tensile load and displacement, after fatigue test the static force was tested to evaluate the force when device failure occurred. The test result demonstrated that there was no significant difference between the proposed device and predicate device.

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 K113091
Product Code	MBI	MBI
Classification	II	II
Regulation Number	CFR 888.3040	CFR 888.3040
Intended Use	The Button Loop is used for the fixation of soft tissue to bone in orthopedic procedures such as ACL repair.	The RIGIDLOOP™ Cortical Fixation System is used for the fixation of soft tissue to bone in orthopedic procedures such as ACL repair.
Composition	Button Loop Suture	Button Loop Suture
Button	12mm	12mm
Loop	10mm, 15mm, 20mm, 25mm, 30mm, 40mm, 45mm, 50mm, 55mm, 60mm	15mm, 20mm, 25mm, 30mm, 40mm, 45mm, 50mm, 55mm, 60mm
Single Use	Single Use	Single Use
Patient contact material		
Loop	UHMWPE	UHMWPE
Button	Titanium Alloy	Titanium Alloy
Suture	UHMWPE	PE, polyester
Biocompatibility		
Cytotoxicity	No cytotoxicity	Comply with ISO 10993 standards
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	
Sterilization		
Method	Ethylene Oxide	Ethylene Oxide
SAL	10^{-6}	10^{-6}
Endotoxin Limit	20EU/device	20EU/device
Labeling	Conform with 21 CFR Part 801	Conform with 21 CFR Part 801

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.