October 19, 2020

Anrei Medical (Hangzhou) Co., Ltd
% Diana Hong
General Manager
Mid-Link Consulting Co., Ltd
P.O. Box 120-119
Shanghai, 200120
CHINA

Re: K201771
Trade/Device Name: Single Use Rotatable and Repositionable Hemoclip
Regulation Number: 21 CFR 876.4400
Regulation Name: Hemorrhoidal Ligator
Regulatory Class: II
Product Code: PKL
Dated: September 16, 2020
Received: September 17, 2020

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,

For Shani P. Haugen, Ph.D.
Assistant Director
DHT3A: Division of Renal, Gastrointestinal,
Obesity and Transplant Devices
OHT3: Office of GastroRenal, ObGyn,
General Hospital and Urology 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)*
K201771

Device Name
Single Use Rotatable and Repositionable Hemoclip

Indications for Use *(Describe)*
Single Use Rotatable and Repositionable Hemoclip is indicated for clip placement within the Gastrointestinal (GI) tract for the purpose of:
1) Endoscopic marking
2) Hemostasis for:
Mucosal/sub-mucosal defects < 3cm,
Bleeding ulcers,
Arteries < 2mm,
Polyps < 1.5cm in diameter,
Diverticula in the colon,
3) As a supplementary method, closure of GI tract luminal perforations < 20mm that can be treated conservatively

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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Exhibit #8 510(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: K201771

1. Date of Preparation: 09/07/2020

2. Sponsor Identification

Anrei Medical (Hangzhou) Co., Ltd
No.3 Ave. 8, Hangzhou Economic Development Area, Hangzhou, 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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P.O. Box 120-119, Shanghai, 200120, China

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Fax: 360-925-3199
Email: info@mid-link.net

4. Identification of Proposed Device

Trade Name: Single Use Rotatable and Repositionable Hemoclip
Common Name: Hemorrhoidal ligator

Regulatory Information

Classification Name: Hemorrhoidal ligator
Classification: II;
Product Code: PKL;
Regulation Number: 21CFR 876.4400
Review Panel: Gastroenterology/Urology;

Indication for Use Statement:

Single Use Rotatable and Repositionable Hemoclip is indicated for clip placement within the Gastrointestinal (GI) tract for the purpose of:

1. Endoscopic marking,
2. Hemostasis for:

Mucosal/sub-mucosal defects <3cm,
Bleeding ulcers,
Arteries < 2mm,
Polyps < 1.5cm in diameter,
Diverticula in the colon,
3. As a supplementary method, closure of GI tract luminal perforations < 20mm that can be treated conservatively.

Device Description

The proposed device is a sterile, single-use endoscopic clipping device. It is consisted of two main components: the delivery system and the clip. The delivery system is available in three different working length. The clip is deployed from the delivery system during use. The hemoclip jaws can be opened and closed up to five times prior to deployment, aiding in repositioning of the clip at the lesion site.

5. Identification of Predicate Devices

Predicate Device 1
510(k) Number: K161463
Product Name: SureClip(TM) Repositionable Hemostasis Clip

Predicate Device 2
510(k) Number: K152001
Product Name: Sterile Repositionable Hemostasis Clipping Device

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 10993-5:2009 Biological evaluation of medical devices- Part 5: Test for in vitro cytotoxicity
- 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: Test for irritation and delayed-type hypersensitivity
- ISO 10993-11: 2017 Biological evaluation of medical devices - Part 11: Tests for systemic toxicity
- ASTM F1929-15 Standard test method for detecting seal leaks in porous medical packaging by dye penetration.
- ASTM F88/F88M-15 standard method for seal strength of flexible barrier materials
- USP 42 NF 37 <151> Pyrogen Test

Dimension test was performed on the proposed device and the test result demonstrated that the device can meet its design specification requirement.

Performance test was performed on both the proposed device and predicate device and the test result demonstrated that there was no significant difference between them, the test include following items

Mechanical Integrity of Clip Assembly
Clamping Strength Testing
Tensile Strength Testing
Release Force Testing
Rotation Testing
Repositionability

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 1 K161463	Predicate Device 2 K152001
Product Code	PKL	PKL	PKL
Regulation Number	21CFR 876.4400	21CFR 876.4400	21CFR 876.4400
Indication for Use	Single Use Rotatable and Repositionable Hemoclip is indicated for clip placement within the Gastrointestinal (GI) tract for the purpose of: 1. Endoscopic marking, 2. Hemostasis for: Mucosal/sub-mucosal defects <3cm, Bleeding ulcers, Arteries < 2mm, Polyps < 1.5cm in diameter, Diverticula in the colon, 3. As a supplementary method, closure of GI tract luminal perforations < 20mm that can be treated conservatively.	The SureClip(TM) Repositionable Hemostasis Clip is indicated for endoscopic clip placement within the gastrointestinal tract for the purpose of: (1) endoscopic marking, (2) hemostasis for (a) mucosal / sub-mucosal defects < 3cm, (b) bleeding ulcers, (c) polyps < 1.5cm in diameter, (d) diverticula in the colon, (3) as a supplementary method, closure of GI tract luminal perforations <20mm that can be treated conservatively	The Sterile Repositionable Hemostasis Clipping Device is indicated for endoscopic clip placement within the gastrointestinal tract for the purpose of: (1) endoscopic marking, (2) hemostasis for (a) mucosal / sub-mucosal defects < 3cm, (b) bleeding ulcers, (c) polyps < 1.5cm in diameter, (d) diverticula in the colon, (3) as a supplementary method, closure of GI tract luminal perforations <20mm that can be treated conservatively.
Configuration	Delivery system and jaw	Delivery system and jaw	Delivery system and jaw
Rotation function	rotatable	rotatable	rotatable
Open width	9mm, 11mm, 13mm and 16mm	8mm, 11mm and 16mm	11mm
Minimal working channel	2.8mm	2.8mm	2.8mm

Working length	1650mm, 1950mm, 2300mm and 2700mm	1650mm, 1950mm and 2350mm	1650mm, 1950mm, 2350mm and 2700mm
Single Use	Single Use	Single Use	Single Use
Labeling	Comply with 21 CFR Part 801	Comply with 21 CFR Part 801	Comply with 21 CFR Part 801
Biocompatibility			
Cytotoxicity	No cytotoxicity	Comply with ISO 10993 standards	Comply with ISO 10993 standards
Skin Sensitization	No skin sensitization		
Irritation	No irritation		
Acute Systemic Toxicity	No acute toxicity		
Sub-acute Systemic Toxicity	No sub-acute toxicity		
Pyrogen	No pyrogen		
Sterilization			
Method	Ethylene oxide	Ethylene oxide	Ethylene oxide
SAL	10^{-6}	10^{-6}	10^{-6}
Endotoxin Limit	20EU	20EU	20EU
Shelf life	3 years	3 years	3 years

9. Substantially Equivalent (SE) Conclusion

The nonclinical tests demonstrate that the device is as safe, as effective, and performs as well as the legally marketed device predicate device.