June 7, 2024

Ningbo Xinwell Medical Technology Co., Ltd
% Diana Hong
General Manager
Mid-Link Consulting Co, Ltd.
P.O. Box 120-119
Shanghai, 200120
CHINA

Re: K232969
Trade/Device Name: Disposable Hemostatic Clips
Regulation Number: 21 CFR 876.4400
Regulation Name: Hemorrhoidal Ligator
Regulatory Class: Class II
Product Code: PKL
Dated: September 21, 2023
Received: May 9, 2024

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device"

(https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

Sivakami Venkatachalam -S

for
Shanil 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: 06/30/2023
See PRA Statement below.

Submission Number *(if known)*

K232969

Device Name

Disposable Hemostatic Clips

Indications for Use *(Describe)*

The Disposable Hemostatic Clips is indicated for Endoscopic clip placement within the Gastrointestinal tract in adult populations only via a straight or side viewing flexible endoscope 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.
E) Arteries < 2 mm.
F) Prophylactic clipping to reduce the risk of delayed bleeding post lesion resection.
3) As a supplementary method, closure of GI tract luminal perforations <20mm that can be treated conservatively
4) Anchoring to affix jejunal feeding tubes to the wall of the small bowel

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.

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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: K232969

1. Date of Preparation: 06/03/2024

2. Sponsor Identification

Ningbo Xinwell Medical Technology Co., Ltd.
No.188 Binjiang Road, Cixi High-tech Industrial Development Zone, Cixi City, Zhejiang,P.R. China

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3. Designated Submission Correspondent

Ms. Diana Hong (Primary Contact Person)
Ms. Tingting Su (Alternative Contact Person)

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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: Disposable Hemostatic Clips
Common Name: Hemostasis Clipping Device

Regulatory Information
Classification Name: Hemorrhoidal Ligator;

Classification: II,
Product Code: PKL,
Regulation Number: 21CFR 876.4400
Review Panel: Gastroenterology/Urology,

Indications for Use:
The Disposable Hemostatic Clips is indicated for Endoscopic clip placement within the Gastrointestinal tract in adult populations only via a straight or side viewing flexible endoscope 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.
E) Arteries < 2 mm.
F) Prophylactic clipping to reduce the risk of delayed bleeding post lesion resection.
3) As a supplementary method, closure of GI tract luminal perforations <20mm that can be treated conservatively
4) Anchoring to affix jejunal feeding tubes to the wall of the small bowel.

5. Device Description

The proposed device is consisted of a clip section and a delivery section. The delivery section include: slide bar, slip ring, protective sleeve, rotation head, coated spring tube, slip ring holder, traction assembly，connecting tube, decoupled piece, decoupled shrapnel, rotation sleeve. And the clip section include: clip, sliding block, shaft and rocker arm. The clip is made of stainless steel. The clip can be opened and closed more than five times prior to deployment, aiding in repositioning of the clip at the lesion site. The proposed device is available in single ring and three ring models, and each case is divided into rotatable and non-rotatable clip. The effective length of the proposed device includes 1250mm, 1650mm, 2350mm and 2700mm, and the opening width is 9mm, 11mm, 13mm and 16mm. The proposed devices are provided in sterile and single use.

6. Identification of Predicate Device

Predicate Device
510(k) Number: K202333
Product Name: Lockado™ Repositionable Hemostasis Clip

7. 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: Test 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 10993-10:2021 Biological evaluation of medical devices Part 10: Tests for skin sensitization
- ISO 10993-11: 2017 Biological evaluation of medical devices - Part 11: Tests for systemic toxicity
- ISO 10993-23:2021 Biological evaluation of medical devices Part 23: Tests for irritation
- 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
- ASTM F1886 / F1886M-16, Standard Test Method for Determining Integrity of Seals for Flexible Packaging by Visual Inspection
- USP <85> Bacterial Endotoxins Test
- ASTM D4169-22 Standard Practice for Performance Testing of Shipping Containers and Systems

Performance testing

The following bench tests were performed on the Disposable Hemostatic Clips:

- Appearance
- Rotation performance
- Release force
- Clamping strength
- Relocation
- Tensile strength
- Dimension
- Mechanical integrity of clip assembly
- Scope compatibility/usability
- Endoscope damage
- Torque
- Clip approach
- Three ring handle strength

Above all tests were passed and demonstrated the result can meet the product requirements.

Biocompatibility testing

The biocompatibility evaluation for the proposed device was conducted in accordance with FDA Guidance, Use of International Standard ISO 10993-1, 'Biological Evaluation of Medical Devices Part 1: Evaluation and Testing within a risk management process" issued on September 4, 2020. The following tests were conducted for the clip component of Disposable Hemostatic Clips:

- Cytotoxicity
- Irritation
- Skin Sensitization
- Acute Systemic Toxicity
- Sub-acute Systemic Toxicity
- Genotoxicity
- Pyrogenicity
- Implantation Test

The following tests were conducted for the delivery component of Disposable Hemostatic Clips:

- Cytotoxicity
- Irritation
- Skin Sensitization
- Acute Systemic Toxicity
- Pyrogenicity

Sterility, Shipping, and Shelf -life

The proposed device sterilization process using Ethylene Oxide (EO) has been validated in accordance with ISO 11135:2014 to achieve a sterility assurance level (SAL) of 10^{-6}. EO and Ethylene Chlorohydrin (ECH) residuals were below the limits specified in ISO 10993-7:2008. Bacterial Endotoxin Levels were below the level of 2.15 EU/device in accordance with USP <85>. Both baseline and accelerated shelf life testing were conducted demonstrating the device will perform as intended to support the proposed 3 year shelf-life.

- Package integrity test – after environmental conditioning, simulated transportation testing in accordance to ASTM D4169-22 on final, packaged, and sterile device.
- Sterile Barrier Packaging performed on the proposed device:
  - Seal Strength ASTM F88/F88-15
  - Dye penetration ASTM F1929-15
  - Visual Inspection ASTM F1886/F1886M-16
- Shelf-life of 3-years is validated using FDA recognized standard ASTM F1980 -16 Standard Guide for Accelerated Aging of Sterile Barrier Systems for Medical Devices.

8. Clinical Test Conclusion

No clinical study is included in this submission.

9. Substantially Equivalent (SE) Comparison

Table 1. General Comparison

Item	Proposed Device K232969	Predicate Device K202333	Remark
Product Code	PKL	PKL	Same
Regulation Number	21CFR 876.4400	21CFR 876.4400	Same
Indications for Use	The Disposable Hemostatic Clips is indicated for Endoscopic clip placement within the Gastrointestinal tract in adult populations only via a straight or side viewing flexible endoscope 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. E) Arteries < 2 mm. F) Prophylactic clipping to reduce the risk of delayed bleeding post lesion resection. 3) As a supplementary method, closure of GI tract luminal perforations <20mm that can be treated conservatively 4) Anchoring to affix jejunal feeding tubes to the wall of the small bowel;	The Lockado™ Repositionable Hemostasis Clip is indicated for Endoscopic clip placement within the Gastrointestinal tract in adult patients only via a straight or side viewing flexible endoscope 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, (e) Arteries < 2 mm (f) Prophylactic clipping to reduce the risk of delayed bleeding post lesion resection; (3) As a supplementary method, closure of GI tract luminal perforations <20mm that can be treated conservatively (4) Anchoring to affix jejunal feeding tubes to the wall of the small bowel;	Same
Configuration	Delivery system and clip	Delivery system and clip	Same

	assembly	assembly	
Open width	9mm, 11mm, 13mm and 16mm	8mm, 11mm and 16mm, 22mm	Different
Minimal working channel	2.8mm	2.8mm	Same
Working length	1250mm, 1650mm, 2350mm and 2700mm	1650mm 1950mm, 2350mm and 2700mm	Different
Ring number	Single ring and three rings	Single ring	Different
Single Use	Single Use	Single Use	Same
Labeling	Comply with 21 CFR Part 801	Comply with 21 CFR Part 801	Same
Material			
Clip assembly	Stainless Steel (SUS316L)	Unknown	Different
	Stainless Steel (SUS631)		
	Stainless Steel (SUS316F)		
Traction assembly	Stainless Steel (SUS304)		
Outer tube assembly	Stainless Steel (SUS304)		
	Stainless Steel (SUS316F)		
	Polyethylene (PE)		
Slide bar	Acrylonitrile Butadiene Styrene (ABS)		
Slip ring	Thermoplastic Elastomer (TPE)		
Rotation head	Acrylonitrile Butadiene Styrene (ABS)		
Protective sleeve	Thermoplastic Elastomer (TPE) High pressure-low density polyethylene (LDPE)		
Biocompatibility for Delivery system			
Cytotoxicity	No cytotoxicity	Comply with ISO 10993 standards	Same
Skin Sensitization	No skin sensitization		
Irritation	No irritation		
Acute Systemic Toxicity	No acute toxicity		
Sub-acute Systemic Toxicity	No sub-acute toxicity		
Biocompatibility for clip assembly			
Cytotoxicity	No cytotoxicity	Comply with ISO 10993 standards	Same
Skin Sensitization	No skin sensitization		
Irritation	No irritation		
Acute Systemic Toxicity	No acute toxicity		
Sub-acute Systemic Toxicity	No sub-acute toxicity		

Implantation	No abnormal reaction		
Genotoxicity	No genotoxicity		
Sterilization			
Method	Ethylene oxide	Ethylene oxide	Same
SAL	10^{-6}	10^{-6}	Same
Endotoxin Limit	20EU	20EU	Same

Different - Open width

The open width for proposed device is available in 9mm, 11mm, 13mm and 16mm four different specifications. The predicate device is available in 8mm, 11mm 16mm and 22mm four different specifications. The 9mm and 13mm specification is different from predicate device. However, these specifications can be covered in the open width range of predicate device. Different working length devices will be selected by physician per patient's condition. Therefore, this difference will not raise new questions on safety and effectiveness of the proposed device.

Different - Working length

The working length for proposed device is available in 1250mm, 1650mm, 2350mm and 2700mm. The working length of predicate device is available in 1650mm 1950mm, 2350mm and 2700mm. Different working length devices will be selected by physician per patient's condition. The length for proposed device of 1650mm, 2350mm and 2700mm can be covered by predicate device length range. Although 1250mm effective length device are not included in the effective length range of the predicate device, it is very close to the minimum length of predicate device. Therefore, this difference will not raise new questions on safety and effectiveness of the proposed device.

Different- Ring number

The proposed device has two models of single ring and three rings, while the predicate device only has single ring model. Single ring models can be covered by predicate device. The sponsor also has performed ring tension tests on the three-ring model of the proposed device, and the test results show that the three-ring model is similar as predicate device, and it can withstand the forces generated during clinical use. Therefore, this difference will not raise new questions on safety and effectiveness of the proposed device.

Different-Material

The material for the predicate device is unknown. However, biocompatibility test has been conducted on the proposed device for contact materials and the test result can meet the requirements of ISO 10993 series standard. Therefore, this difference will not raise new questions on safety and effectiveness of the proposed device.

10. Conclusion

The conclusion drawn from the non-clinical tests demonstrates that the subject device in 510(k) submission, Disposable Hemostatic Clips, is as safe, as effective, and performs as well as or better than the legally marketed

predicate device cleared under K202333.