May 1, 2023

Jiangsu Vedkang Medical Science and Technology Co., Ltd.
% Diana Hong
General Manager
Mid-Link Consulting Co., Ltd
P.O Box 120-119
Shanghai, 2000120
CHINA

Re: K222146
Trade/Device Name: Disposable Endoscopic Hemoclip
Regulation Number: 21 CFR 876.4400
Regulation Name: Hemorrhoidal Ligator
Regulatory Class: Class II
Product Code: PKL

Dear Diana Hong:

The Food and Drug Administration (FDA) is sending this letter to notify you of an administrative change related to your previous substantial equivalence (SE) determination letter dated March 28, 2023. Specifically, FDA is updating this SE Letter as an administrative correction to update the company name.

Please note that the 510(k) submission was not re-reviewed. For questions regarding this letter please contact Shanil Haugen, OHT3: Office of GastroRenal, ObGyn, General Hospital and Urology Devices,.

Sincerely,

Shanil P. Haugen -S

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

March 28, 2023

Jiangsu Horizon Medical Science & Technology Co., Ltd.
℅ Diana Hong
General Manager
Mid-Link Consulting Co., Ltd
P.O Box 120-119
Shanghai, 2000120
CHINA

Re: K222146
Trade/Device Name: Disposable Endoscopic Hemoclip
Regulation Number: 21 CFR 876.4400
Regulation Name: Hemorrhoidal ligator
Regulatory Class: Class II
Product Code: PKL
Dated: February 16, 2023
Received: February 23, 2023

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,

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.

510(k) Number *(if known)*
K222146

Device Name
Disposable Endoscopic Hemoclip

Indications for Use *(Describe)*
It 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

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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PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

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: K222146

1. Date of Preparation: 02/18/2023

2. Sponsor Identification

Jiangsu Vedkang Medical Science & Technology Co., Ltd.
No. 52, Guoxiang Road, Wujin Economic Development Zone, Changzhou 213149, Jiangsu, P.R. China

Establishment Registration Number: 3013526170

Contact Person: Lin Zhang
Position: International Registrar
Tel: +86-519-69877755
Fax: +86-519-69877753
Email: rateam@vedkang.com

3. Designated Submission Correspondent

Ms. Diana Hong (Primary Contact Person)
Ms. Tingting Su (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: Disposable Endoscopic Hemoclip
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:
It 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.

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 include: metal cap, spring sheath, pulling wire component, coating layer, protective tube, core rod, and slider. The clip include: clip components and sleeve, and it is deployed from the delivery system during use. The hemoclip can be opened and closed up to five times prior to deployment, aiding in repositioning of the clip at the lesion site. The device is available in four clip opening widths, which are 9mm, 11mm, 13mm and 16mm, and the device effective length is available in 1600mm, 1800mm, 2300mm, 2600mm.

5. Identification of Predicate Device

Predicate Device
510(k) Number: K182556
Product Name: SureClip Repositionable Hemostasis Clip

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 10993-6:2017 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: 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
- ASTM F1886 / F1886M-16, Standard Test Method for Determining Integrity of Seals for Flexible Packaging by Visual Inspection
- USP <85> Bacterial Endotoxins Test
- USP 43 <151> Pyrogen Test
- ASTM F2052-15 Standard Test Method for Measurement of Magnetically Induced Displacement Force on Medical Devices in the Magnetic Resonance Environment
- ASTM F2213-17 Standard Test Method for Measurement of Magnetically Induced Torque on Medical Devices in the Magnetic Resonance Environment
- ASTM F2182-19 e2, Standard Test Method for Measurement of Radio Frequency Induced Heating On or Near Passive Implants During Magnetic Resonance
- ASTM F2119-07(Reapproved 2013), Standard Test Method for Evaluation of MR Image Artifacts from Passive Implants
- ASTM D4169:2016 Standard Practice for Performance Testing of Shipping Containers and Systems

Performance testing

- The following bench tests were performed on the Disposable Endoscopic Hemoclip:Dimension
- Rotation test
- Relocation test
- Mechanical integrity test
- Tensile strength test
- Release force test
- Clamping strength test

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 Endoscopic Hemoclip:

- Cytotoxicity
- Irritation
- Skin Sensitization
- Acute Systemic Toxicity
- Pyrogenicity
- Implantation Test
- Chemical Characterization Study

The following tests were conducted for the delivery component of Disposable Endoscopic Hemoclip:

- 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 20 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 5 year shelf-life.

- Package integrity test – after environmental conditioning, simulated transportation testing in accordance to ASTM D4169-16 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.

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 K182556	Remark
Product Code	PKL	PKL	Same
Regulation Number	21CFR 876.4400	21CFR 876.4400	Same
Indications for Use	It is indicated for Endoscopic clip placement within the Gastrointestinal tract 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.	The SureClip 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	Same
Configuration	Delivery system and clip assembly	Delivery system and clip assembly	Same
Rotation function	Rotatable	Rotatable	Same
Open width	9mm, 11mm, 13mm and 16mm	8mm, 11mm and 16mm	Different
Minimal working channel	2.8mm	2.8mm	Same
Working length	1600mm, 1800mm, 2300mm and 2600mm	1650mm and 2350mm	Different
Single Use	Single Use	Single Use	Same
Labeling	Comply with 21 CFR Part 801	Comply with 21 CFR Part 801	Same

Material			
Clip components	SUS631 Stainless steel	Unknown	Different
Sleeve	SUS316F	Unknown	
Metal cap	SUS303 Stainless steel	Unknown	
Spring sheath	SUS304	Unknown	
Pulling wire component	SUS304	Unknown	
Coating layer	Polyethylene (PE), Ethylene-vinyl Acetate (EVA) and Purple Pigment	Unknown	
Protective tube	SUS304	Unknown	
Core rod	Acrylonitrile Butadiene Styrene (ABS) and Thermoplastic Elastomer (TPE)	Unknown	
Slider	Acrylonitrile Butadiene Styrene (ABS) and Thermoplastic Elastomer (TPE)	Unknown	
Biocompatibility			
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		
Sterilization			
Method	Ethylene oxide	Ethylene oxide	Same
SAL	10^{-6}	10^{-6}	Same
Endotoxin Limit	20EU	20EU	Same

9. Conclusion

The conclusion drawn from the non-clinical tests demonstrates that the subject device in 510(k) submission, Disposable Endoscopic Hemoclip, is as safe, as effective, and performs as well as or better than the legally marketed predicate device cleared under K182556.