January 2, 2025

Jiangxi ZhuoRuiHua Medical Instrument Co., Ltd.
% Xiaoqing Xue
Registration Engineer
Sinow Medical AS
Høyteknologisenteret Thormøhlens Gate 55
Bergen, 5008
Norway

Re: K241005
Trade/Device Name: Haemostasis Clips
Regulation Number: 21 CFR 876.4400
Regulation Name: Hemorrhoidal Ligator
Regulatory Class: Class II
Product Code: PKL
Dated: December 4, 2024
Received: December 4, 2024

Dear Xiaoqing Xue:

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.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

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,

Shanil P. Haugen -S

Shanil P. Haugen, Ph.D.
Assistant Director
DHT3A: Division of Renal, Gastrointestinal, Obesity, and Transplant Devices
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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: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K241005

Device Name

Haemostasis Clips

Indications for Use *(Describe)*

The The Haemostasis Clips are indicated for endoscopic clip placement within the gastrointestinal 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;
Prophylactic clipping to reduce the risk of delayed bleeding post lesion resection.
3.Anchoring to affix jejunal feeding tubes to the wall of the small bowel;
4.As a supplementary method, closure for 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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510(K) Summary

1. Submitter

Submitter: Jiangxi ZhuoRuiHua Medical Instrument Co., Ltd.
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Date Prepared: Apirl 12, 2024

2. Designated Submission Correspondent

Company: Sinow Medical AS
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Contact Person: Xiaoqing Xue
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3. Subject Device

Trade name/common name: Haemostasis Clips
Regulatory Class: II
Regulation Number: 876.4400
Product Codes: PKL
Classification Name: Hemorrhoidal ligator

4. Primary Predicate Device

Manufacturer: Hangzhou AGS MedTech CO., Ltd
Trade name: Hemoclip
510(K) Number: K172727
Regulation Number: 21 CFR 876.4400
Product Codes: PKL
Classification Panel: Gastroenterology/Urology
Classification Name: Hemorrhoidal Ligator

5. Device Description

The Haemostasis Clips are sterile devices consisting of a pre-loaded, radiopaque, single-use, endoscopic clipping device consisting of two main components: the delivery system and the clip part. The delivery system consists of a handle assembly and delivery catheter assembly. The delivery system is constructed using stainless steel and polyester materials. The delivery system will allow for the device to rotate at the distal end. The delivery system is offered in 1650mm, 1950mm and 2350mm working lengths.

The clip part consists of a stainless steel tightening capsule, movable pin and clip arms. The clip is deployed from the delivery system during use. The hemoclip jaws are engineered such that they can be opened and closed up to five times prior to deployment, aiding in repositioning of the clip at the lesion site. Re-opening, closing, and rotation capability may be limited by clinical circumstances and patient anatomy. There are no associated accessories included with this device.

6. Intended Use/Indications for Use

The Haemostasis Clips are indicated for endoscopic clip placement within the gastrointestinal 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
- Prophylactic clipping to reduce the risk of delayed bleeding post lesion resection

3. Anchoring to affix jejunal feeding tubes to the wall of the small bowel
4. As a supplementary method, closure for GI tract luminal perforations<20mm that can be treated conservatively.

7. Comparison of Technological Characteristics

Attribute	Haemostasis Clips (Subject Device)	Hemoclip (Predicate device K172727)	Comment
Regulation Number	21 CFR 876.4400	21 CFR 876.4400	Same
Regulation Name	Hemorrhoidal Ligator	Hemorrhoidal Ligator	Same
Regulatory Class	Class II	Class II	Same
Product Code	PKL	PKL	Same

Indications for Use	The Haemostasis Clips are indicated for endoscopic clip placement within the gastrointestinal tract for the purpose of: Endoscopic marking Hemostasis for -Mucosal/sub-mucosal defects <3cm -Bleeding ulcers -Arteries<2mm -Polyps<1.5cm in diameter -Diverticula in the colon -Prophylactic clipping to reduce the risk of delayed bleeding post lesion resection 3.Anchoring to affix jejunal feeding tubes to the wall of the small bowel 4.As a supplementary method, closure for GI tract luminal perforations<20mm that can be treated conservatively.	The disposable hemoclip is indicated for endoscopic clip placement within the gastrointestinal 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 -Prophylactic clipping to reduce the risk of delayed bleeding post lesion resection 3.Anchoring to affix jejunal feeding tubes to the wall of the small bowel 4.As a supplementary method, closure for GI tract luminal perforations<20mm that can be treated conservatively.	Same
Principle of Operation	Endoscopic accessory used to deliver metal clips to the GI tract.	Endoscopic accessory used to deliver metal clips to the GI tract.	Same
Repositionable Clip?	Yes	Yes and No (depending on model)	Same
Minimum Endoscopic Working Channel	2.8mm	2.8mm	Same
Working length	1650mm, 1950mm and 2350mm	1650mm, 1950mm and 2350mm	Same
Outer tube diameter	2.6mm	2.6mm	Same
Clip opening width	10mm, 12mm and 15mm	9mm, 11mm, 13mm	Different[1]
Single use only	Yes	Yes	Same

Sterilization	EO	EO	Same
Clip material	Stainless Steel (SUS 631 and SUS303)	Stainless Steel (SUS 631)	Similar

Discussion of difference [1]: The subject largest device clip opening width is not in the predicate device clip opening width dimension range. Although differences exist between clip opening width, the subject device have the same design, materials and intended performance between different specifications, only increased width. Furthermore, the largest clip opening width model is selected as representative sample to conduct bench performance testing and the test result showed to meet the requirement. Therefore, we considered that this difference does not raise new questions of safety or effectiveness.

8. Non-Clinical Testing

8.1. Performance Testing-Bench

Jiangxi ZhuoRuiHua Medical Instrument Co., Ltd. has performed the following non-clinical laboratory testing to determine substantial equivalence.

Test	Result
Appearance	Pass
Size	Pass
Open and Close	Pass
Rotation property	Pass
Separation and clamping properties	Pass
Clip release force testing	Pass
Clip hardness	Pass
Corrosion	Pass
Connection strength before clip released	Pass
Breaking force of the delivery part	Pass
Clamping force maintenance	Pass
Chemical properties	Pass

The above bench tests were performed on Haemostasis Clips: Appearance, Size, Chemical properties, Physical properties including Open and Close, Rotation property, Separation and clamping properties, Clip release force testing, Clip hardness, Corrosion resistance, Connection strength before clip released, Breaking force of the delivery part and Clamping force maintenance. The results of all testing meet the requirement.

8.2. Biocompatibility testing

The contact classification for the Haemostasis Clips of the subject device is a surface contact device that directly contact with the mucosal membrane (with the duration time 24h~30d). The

biocompatibility evaluation for the subject device was conducted in accordance with ISO 10993-1:2018 Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process and 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", Guidance for Industry and Food and Drug Administration Staff. The results of biocompatibility testing included in the table below demonstrate that the device meets biological safety requirements per ISO 10993-1 for mucosal membrane contact device.

Test	Standard	Result
In vitro cytotoxicity	ISO 10993-5	Non-cytotoxic
Skin sensitization	ISO 10993-10	Non-sensitive
Intracutaneous reactivity	ISO 10993-10	Non- irritation
Acute systemic toxicity	ISO 10993-11	Non-acute systemic toxicity
Pyrogen	ISO 10993-11	Non-pyrogenic
Hemolysis test	ISO 10993-4	Non Hemolysis reaction
Sub chronic toxicity	ISO 10993-11	Non-Sub chronic toxicity
Implantation effect	ISO 10993-6	Non-Implantation effect

8.3. Sterilization and shelf-life testing

The subject device is sterilized using Ethylene Oxide. The sterilization validation has been performed in accordance with the principles of ISO 11135:2014 Sterilization of health-care products - Ethylene oxide - Requirements for the development, validation and routine control of a sterilization process for medical devices. A sterility assurance level (SAL) of 10^{-6} has been demonstrated. The device meets EO residuals per ISO 10993-7.
A shelf-life of 3 years has been established based on accelerated aging testing.

9. Conclusion

The subject and predicate device share the same indications and technological characteristics. The subject device has the identical intended use as the predicate device. The subject device and predicate devices are substantially equivalent with only minor differences. These differences do not raise new questions of safety or effectiveness. The nonclinical performance data submitted in the documents demonstrate that the subject device is as safe, as effective, and performs as well as the predicate device. Based on the information provided in this premarket notification, Jiangxi ZhuoRuiHua Medical Instrument Co., Ltd. has demonstrated that the proposed device Haemostasis Clips are substantially equivalent to Hangzhou AGS MedTech CO., Ltd's currently marketed Hemoclip, K172727.