November 12, 2025

Hangzhou AGS MedTech Co.,Ltd.
Xufan Chi
RA
Building 2, 5 and 7, No.389 Xingzhong Road
Linping District
Hangzhou, Zhejiang 311103
China

Re: K252271
Trade/Device Name: Hemoclip
Regulation Number: 21 CFR 876.4400
Regulation Name: Hemorrhoidal Ligator
Regulatory Class: Class II
Product Code: PKL
Dated: August 14, 2025
Received: August 14, 2025

Dear Xufan Chi:

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,

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: 07/31/2026
*See PRA Statement below.*

Submission Number *(if known)*

K252271

Device Name

Hemoclip

Indications for Use *(Describe)*

The 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

3. Anchoring to affix jejunal feeding tubes to the wall of the small bowel.
4. 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.***

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
*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

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## CH2.03.1 Submitter

| | |
|---|---|
| Submitted by/Owner: | Hangzhou AGS MedTech Co., Ltd.<br>Building 2, 5 and 7, No.389 Xingzhong Road, Linping District, 311103 Hangzhou, Zhejiang, PEOPLE'S REPUBLIC OF CHINA |
| Establishment Registration Number: | 3010288205 |
| Registration Status: | Active |
| Contact Person: | Xufan Chi<br>Building 2, 5 and 7, No.389 Xingzhong Road, Linping District, 311103 Hangzhou, Zhejiang, PEOPLE'S REPUBLIC OF CHINA<br>Phone: +86-0571-87671223<br>Fax: +86-0571-87671225<br>Email: chixf@bioags.com |
| Date Prepared: | August 7, 2025 |

## CH2.03.2 Proposed Device

| | |
|---|---|
| Trade Name: | / |
| Device Name: | Hemoclip |
| Common Name: | Hemoclip |
| Regulation class: | Class II |
| Regulation Number: | 876.4400 |
| Regulation Description: | Hemorrhoidal ligator |
| Review Panel: | Gastroenterology/Urology |
| Product Code: | PKL |
| Product Code Name: | Hemostatic Metal Clip For The Gi Tract |

## CH2.03.3 Predicate Device

| | |
|---|---|
| Trade Name: | / |
| Device Name: | Hemoclip |
| Common Name: | Hemoclip |
| 510(k) Number: | K211787 |
| Regulation class: | Class II |
| Regulation Number: | 876.4400 |
| Regulation Description: | Hemorrhoidal ligator |
| Review Panel: | Gastroenterology/Urology |
| Product Code: | PKL |

| | |
|---|---|
| Product Code Name: | Hemostatic Metal Clip For The Gi Tract |

**CH2.03.4 Device Description**

Hemoclip consists of Release part and Clip part. Clip part consists of Clip and Frap Tube. Release part consists of Spring End, Plastic Coated Spring Tube / Spring Tube and Handle assembly. EO Sterilization and use for single use only.

**CH2.03.5 Indications for use**

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

**CH2.03.6 A description of the accessories**

For this proposed device Hemoclip, no other medical devices and no other products that are not devices provided with it as accessories.

In clinical use, the distal-end of the product needs to enter the digestive tract through the working channel of the endoscope, though there's no physical connection.

And this proposed device Hemoclip have been designed to be used with "Polypectomy snare" and "Polypectomy snare(cold)" from Hangzhou AGS MedTech Co., LTD.

After the operation, the "Polypectomy snare" or "Polypectomy snare(cold)" from Hangzhou AGS MedTech Co., LTD was used to tighten the groove at Frap tube of the " Hemoclip ". After tightening the groove of the tube, the clip was opened and the tissue was separated. After successful removal, the removed clip was placed close to the distal orifice of the endoscope and exited the digestive tract with the endoscope.

Table CH2.03.6 Compatible device

| Device Name: | 510(k) Number/ Listing Number: |
|---|---|
| Polypectomy snare | K221713 |
| Polypectomy snare(cold) | D320785 |

**CH2.03.7 Comparison of Technology Characteristics**

Our proposed device Hemoclip is substantially equivalent to the predicate devices. The differences between the Hemoclip and the predicate devices do not raise any questions regarding its safety and effectiveness. The differences are listed in the table

below:

Table CH2.03.7 Comparison of technical characteristics

| Item | | Proposed device<br>Hangzhou AGS MedTech Co., Ltd. | Predicate device（K211787）<br>Hangzhou AGS MedTech Co., Ltd. | Comparion |
|---|---|---|---|---|
| Technical | Principle of operation(remove) | For 510 series, the released clip could be removed by “Polypectomy snare (cold)” and “Polypectomy snare” (snare with wire diameter between 0.30~0.41mm) manufactured by AGS. There is a locking hook at the end of the clips, when the clip part released after the closing movement, the locking hook forms a buckle with the groove at the lower end of the frap tube, making the two clips self-locking and closing, so as to achieve mechanical suture of the tissue at the lesion. Intraoperative, when operators find close position is not ideal, need to be adjusted to remove the released and closed clip head, they could take a snare product, since the endoscopic clamp inserts, in the perspective of endoscopic, the snare loop goes into the grooves, gradually tightening the snare loop, apply a pressure to the locked hook, press the hooks in, release the lock buckle, so that the two closed clips open, and the closed clip head leave the original lesion site; The snare loop tightens the opened clip head and exits from the human digestive tract together with the endoscope. Then the endoscope was reintroduced into the human digestive tract and the operation continued. | For 510 series, the released clip could be removed by “Polypectomy snare (cold)” and “Polypectomy snare” (snare with wire diameter between 0.36~0.41mm) manufactured by AGS. There is a locking hook at the end of the clips, when the clip part released after the closing movement, the locking hook forms a buckle with the groove at the lower end of the frap tube, making the two clips self-locking and closing, so as to achieve mechanical suture of the tissue at the lesion. Intraoperative, when operators find close position is not ideal, need to be adjusted to remove the released and closed clip head, they could take a snare product, since the endoscopic clamp inserts, in the perspective of endoscopic, the snare loop goes into the grooves, gradually tightening the snare loop, apply a pressure to the locked hook, press the hooks in, release the lock buckle, so that the two closed clips open, and the closed clip head leave the original lesion site; The snare loop tightens the opened clip head and exits from the human digestive tract together with the endoscope. Then the endoscope was reintroduced into the human digestive tract and the operation continued. | Similar.<br>The principle of removing proposed device’ clip and reference device’s clip is the same.<br>Only the minimum value of the wire diameter of the snare used in removing is different. |
| | Performance | 1.Clamping strength;<br>2. Removable performance; | 1.Clamping strength;<br>2. Removable performance; | Different.<br>The performance items 1 to 2 have been |

| Item | | Proposed device<br>Hangzhou AGS MedTech Co., Ltd. | Predicate device（K211787）<br>Hangzhou AGS MedTech Co., Ltd. | Comparion |
|---|---|---|---|---|
| | | | | changed in this special 510(k) submission. |

**CH2.03.8 Applicable Guidance Document**
NA

**CH2.03.9 Performance Data**
The Hemoclip meets all design specifications and medical device standards for biocompatibility (ISO 10993) and sterility (ISO 11135). The non-clinical performance meets the design specification and shows substantial equivalence to the predicated device.

**CH2.03.10 Clinical Test**
No Clinical test is included in this submission.

**CH2.03.11 Conclusion**
In accordance with the Federal Food, Drug and Cosmetic Act, 21 CFR Part 807, Based on the information provided in this premarket notification, Hangzhou AGS MedTech Co., Ltd has demonstrated that proposed device Hemoclip is substantially equivalent to the predicate devices.