August 10, 2026

Hangzhou AGS MedTech Co., Ltd.
Yangping Fu
RA
Bldg. 2, 5 And 7, #389 Xingzhong Rd., Linping District
Hangzhou, Zhejiang 311103
China

Re: K254069
Trade/Device Name: Hemoclip (511 series, 543 series)
Regulation Number: 21 CFR 876.4400
Regulation Name: Hemorrhoidal Ligator
Regulatory Class: Class II
Product Code: PKL
Dated: July 10, 2026
Received: July 10, 2026

Dear Yangping Fu:

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 Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (Preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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 Management System Regulation (QMSR) (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)*

K254069

Device Name

Hemoclip (511 series, 543 series)

Indications for Use *(Describe)*

The hemoclip is indicated for endoscopic clip placement within the digestive tract in adult populations only via a straight or side viewing flexible endoscope 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.

510(k) Summary

We submit this 510(k) Summary as per 21 CFR 807.92, it meets the content and format regulatory requirements.

CH2.03.1 Submitter

Submitted by/Owner:	Hangzhou AGS MedTech Co., Ltd. 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:	Yanping Fu Building 2, 5 and 7, No.389 Xingzhong Road, Linping District, 311103 Hangzhou, Zhejiang, PEOPLE'S REPUBLIC OF CHINA Phone: +86-0571-87671223 Fax: +86-0571-87671225 Email: fuyp@bioags.com
Date Prepared:	July 6, 2026

CH2.03.2 Proposed Device

Trade Name:	/
Device Name:	Hemoclip (511 series, 543 series)
Common Name:	Hemoclip
Regulation class:	Class II
Regulation Number:	876.4400
Regulation Description:	Hemorrhoidal ligator.
Review Panel:	Gastroenterology/Urology
Product Code:	PKL
Common Name:	Hemostatic Metal Clip For The GI Tract

CH2.03.3 Predicate Device

Trade Name:	Lockado™ Repositionable Hemostasis Clip
Device Name:	Lockado™ Repositionable Hemostasis Clip
Common Name:	Hemostasis Clip
510(k) Number:	K202333
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 Clip part and Release part.

For 511 series, clip part consists of Clip, Frap tube and Pin-fin tube. Release part consists of Torque wire, Spring end, Plastic coated spring tube, Sliding handle and Handle assembly. EO Sterilization and use for single use only.

For 543 series, clip part consists of Clip and Frap tube. Release part consists of Spring end, Plastic coated spring tube, Sliding handle and Handle assembly. EO Sterilization and use for single use only.

CH2.03.5 Indication for use statement

The hemoclip is indicated for endoscopic clip placement within the digestive tract in adult populations only via a straight or side viewing flexible endoscope 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, no other medical devices and no other products are 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 straight flexible endoscope, though there’s no physical connection.

The distal-end of the 5431 series needs to enter the digestive tract through the working channel of the straight or side viewing flexible endoscope, though there’s no physical connection.

And our proposed device Hemoclip have been designed to be used individually.

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 Hangzhou AGS MedTech Co., Ltd.	Predicate device (K202333) Micro-Tech (Nanjing) Co., Ltd.	Comparison
Clinical	Intended use	The clip is compatible with endoscope, which is indicated for clip placement within digestive tract for the purpose of mechanical pressure treatment of bleeding of small arteries and pulsation. The device is intended for single use.	/	Different. The predicate device only indicates "Indications for use" in the IFU. The intended use of the proposed device is same as the reference device（K252271）.
Technical	Principle of operation	Principle of Swinging performance(only for 5111 series) When one of the clips comes into contact with the tissue, both clips will swing around the pin-fin tube under the action of an external force. The clip part is attached to the tissue by swinging. Then, by pulling the sliding handle, the clip component completes the closure of the wound in the swinging position.	/	Different. Proposed device has the swinging principle while the predicate device doesn't have. We conduct the Bench test to confirm the effectiveness and safety of swinging performance.
	Claw angle	90°, 135°	Unknown	Different. Our already cleared 510k K211787 has claw angle 90° and 135°. Claw angle test been

<table>
<tr><th colspan="2">Item</th><th>Proposed device
Hangzhou AGS MedTech Co., Ltd.</th><th>Predicate device (K202333)
Micro-Tech (Nanjing) Co., Ltd.</th><th>Comparison</th></tr>
<tr><td></td><td></td><td></td><td></td><td>done for proposed device.
Please refer to CH3.08.</td></tr>
<tr><td></td><td>Performance</td><td>Swinging performance(only for 5111 series)</td><td>/</td><td>Different.
Proposed device has Swinging performance.
We conduct the Bench test to confirm the effectiveness and safety for swinging performance.</td></tr>
<tr><td></td><td>MRI Conditional</td><td> 
MR Unsafe</td><td>MRI Safety Information
 
MR Conditional
A person with the Lockado™ Repositionable Hemostasis Clip may be safely scanned under the following conditions. Failure to follow these conditions may result in injury.
<table><tr><td>Device Name</td><td>Lockado™ Repositionable Hemostasis Clip</td></tr><tr><td>Static Magnetic Field Strength (B0)</td><td>1.5 T or 3.0 T</td></tr></table></td><td>Different.
The proposed device can’t be used in MRI environments and we have clarified in the IFU, Label and Patient implant card. Therefore, its safety risks are lower.
Please refer to CH5.02_Package Labeling and CH5.03_Instruction for</td></tr>
</table>

<table>
<tr><th colspan="2">Item</th><th>Proposed device
Hangzhou AGS MedTech Co., Ltd.</th><th>Predicate device (K202333)
Micro-Tech (Nanjing) Co., Ltd.</th><th>Comparison</th></tr>
<tr><td></td><td></td><td></td><td>
<table>
<tr><td>Maximum Spatial Field Gradient</td><td>40 T/m or 4000 gause/cm</td></tr>
<tr><td>RF Excitation</td><td>Circularly Polarized (CP)</td></tr>
<tr><td>RF Transmit Coil Type</td><td>Volume RF body coil</td></tr>
<tr><td>Operating Mode</td><td>Normal Operating Mode</td></tr>
<tr><td>Maximum Whole-Body SAR</td><td>2 W/kg (normal operating mode)</td></tr>
<tr><td>Maximum Head SAR</td><td>3.2 W/kg (first level control mode)</td></tr>
<tr><td>Scan Duration</td><td>2 W/kg whole-body average SAR for 60 minutes of continuous RF with less than 2 degrees temperature rise</td></tr>
<tr><td>MR Image Artifact</td><td>The pressure of this implant may produce an image artifact at 25mm away from the device.</td></tr>
</table>
Precaution: It is recommended that healthcare providers distribute patient implant cards with the name of the clip and date it was placed.
</td><td>use</td></tr>
<tr><td>Biological</td><td>Main Patient contact Material</td><td>PE, stainless steel</td><td>PE, stainless steel</td><td>Different.
The composition of the predicate device’s</td></tr>
</table>

Item		Proposed device Hangzhou AGS MedTech Co., Ltd.	Predicate device (K202333) Micro-Tech (Nanjing) Co., Ltd.	Comparison
				stainless steel and polymer are unknown. Comparison of biocompatibility equivalence have been done for the proposed device. Biological risks are acceptable. Please refer to CH3.05.06.
Shelf Life		3 years	2 years	Different. Shelf life verification have been done for the proposed device. Please refer to CH3.07.

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.