July 12, 2022

Hangzhou AGS MedTech Co., Ltd.
Yanping Fu, RA Supervisor
Building 5, Building 6, No. 597
Kangxin Road Yuhang District
Hangzhou, Zhejiang 311106
CHINA

Re: K213143
Trade/Device Name: Hemoclip
Regulation Number: 21 CFR 876.4400
Regulation Name: Hemorrhoidal ligator
Regulatory Class: Class II
Product Code: PKL
Dated: May 27, 2022
Received: June 6, 2022

Dear Yanping 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 (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,

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)*
K213143

Device Name
Hemoclip

Indications for Use *(Describe)*
The Hemoclip is indicated for endoscopic clip placement within the digestive 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 digestive 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 (K213143)

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

5.1 Submitter

Submitted by/Owner:	Hangzhou AGS MedTech Co., Ltd. Building 5, Building 6, No.597 Kangxin Road Yuhang District, 311106 Hangzhou, Zhejiang, China
Establishment Registration Number:	3010288205
Registration Status:	Active
Contact Person:	Yanping Fu Phone: 0086-15958493282 Fax: 0086- 0571-87671225 Email: fuyp@bioags.com
Date Prepared:	July. 21, 2021

5.2 Proposed Device

Trade Name:	Hemoclip
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

5.3 Predicate Device and Reference Device

5.3.1Predicate Device

Trade Name:	Hemoclip
Device Name:	Hemoclip
Common Name:	Hemoclip
510(k) Number:	K172727
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

5.3.2 Reference Device

Trade Name:	Single Use Reloadable Clip Applicator,

	Clip, Long Clip, Short Clip, Super Short Clip
Device Name:	Single Use Reloadable Clip Applicator, Clip, Long Clip, Short Clip, Super Short Clip
Common Name:	Endoscopic Clipping Device
510(k) Number:	K183590
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

Trade Name:	Lockado™ Repositionable Hemostasis Clip
Device Name:	Lockado™ Repositionable Hemostasis Clip
Common Name:	Endoscopic Clipping Device
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

5.4 Device Description

Hemoclip consists of Release part and Clip part. Clip part consists of Clip and Frap Tube. Release part consists of Spring End, Spring hose near clip end, Connect end, Plastic Coated Spring Tube / Spring Tube and Handle part. EO Sterilization and use for single use only. For our proposed Hemoclip, the release part could connect and release the clips repeatedly.

We include 5 series for this submission, 55501series, 55502 series, 55503 series, 55504 series and 55505 series. 55501 series and 55502 series are models consist of release part and clip part, and the release part and clip part are already combined, no additional separate clips include, 55501series and 55502 series are reloadable, the release part could connect and release clips repeatedly. 55503 series are models only consist of separate clip part, and the release part of 55501, 55502, 55503 and 55504 series can connect with the separate clip (55503 series) repeatedly. 55504 and 55505 series are models consist of one preloaded Hemoclip (consist of release part and clip part, and the release part and clip part are already combined) and additional separate clips, 55504 series and 55505 series are reloadable, the release part can connect separate clips and release clips repeatedly.

5.5 Indication for use statement

The Hemoclip is indicated for endoscopic clip placement within the digestive 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 of digestive tract luminal perforations<20mm that can be treated conservatively.

5.6 Comparison of Technology Characteristics

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

Table 5.6 Comparison of technical characteristics

Item		**Proposed device** Hangzhou AGS MedTech Co., Ltd.	**Predicate device（K172727）** Hangzhou AGS MedTech Co., Ltd.	**Comparion**
Technical	**Principle of operation**	The clip is opened or closed by operating the sliding handle. After positioning and clamping the related tissues, the sliding handle is operated to separate the clip components from the release part, and the release part then exits the human digestive tract. The clip remained in the alimentary tract for about 1-2 weeks, fell off naturally and was discharged through the intestine and anus. And the release part could connect with additional separate clip part repeatedly, to be a new whole Hemoclip, and realize the intended use.	The clip is opened or closed by operating the sliding handle. After positioning and clamping the related tissues, the sliding handle is operated to separate the clip components from the release part, and the release part then exits the human digestive tract. The clip remained in the alimentary tract for about 1-2 weeks, fell off naturally and was discharged through the intestine and anus.	Different. Our proposed device 555 family could repeatedly connect and release clip.
	Configuration	For 55501 and 55502 series, consists of release part and clip part; For 55504 and 55505 series, there's additional clips for change; For 55503 series, it's the separate clip part.	Consists of release part and clip part;	Different. Our proposed device's release part could connect and release the clips repeatedly.
	Opening span	9 mm,11 mm,13 mm,16 mm,18mm	9mm, 11mm, 13mm,16mm	Different. We add 18mm opening span for more options for doctors.
	Working Length	1650mm, 1950mm, 2150mm, 2300mm	1650mm, 1950mm, 2300mm	Similar. Our proposed device

Item		Proposed device Hangzhou AGS MedTech Co., Ltd.	Predicate device（K172727） Hangzhou AGS MedTech Co., Ltd.	Comparion
				Hemoclip have more working length.
	Connect and release the clip repeatedly performance	Yes	No	Different. Our proposed device have connect and release the clip repeatedly performance.

5.7 Applicable Guidance Document
NA

5.8 Performance Data
The Hemoclip meets all design specifications and medical device standards for shelf life validation (ISO 11607-1/2 and ASTM F 1980-16), packaging validation (ISO 11607-1/2), biocompatibility (ISO 10993) and sterility (ISO 11135). The non-clinical performance meets the design specification and shows substantial equivalence to the predicated device.

5.9 Clinical Test
No Clinical test is included in this submission.

5.10 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 device.