March 3, 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: K211787
Trade/Device Name: Hemoclip
Regulation Number: 21 CFR 876.4400
Regulation Name: Hemorrhoidal ligator
Regulatory Class: Class II
Product Code: PKL
Dated: January 26, 2022
Received: February 2, 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,

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)*
K211787

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
- 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 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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"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

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, Hangzhou, Zhejiang 311106 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:	Jun,1,2021

5.2 Proposed Device

Trade Name:	/
Device Name:	Hemoclip
Common Name:	Endoscope Clipping Device
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

Trade Name:	/
Device Name:	Hemoclip
Common Name:	Endoscope Clipping Device
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

5.4 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. EO Sterilization and use for single use only.

For 510 family, the grooves on the frap tube allow the released clip could be removed by snare loops. If the clip has been deployed, but its position is not satisfactory, or it affects the field of vision, we can remove it.

5.5 Indication for use statement

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
   - 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 GI 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 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:

Item		**Proposed device** Hangzhou AGS MedTech Co., Ltd.	**Predicate device** **（K172727）** Hangzhou AGS MedTech Co., Ltd.	**Comparion**
Model number		510 Family	510 Family，543 Familiy，550 Family	Similar, only 510 family in this submission.
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 delivery device components, and the delivery device 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.	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 delivery device components, and the delivery device then exits the human digestive tract. The clip remained in the alimentary tract for about 1-2 weeks, fell off naturally and	Different. Our proposed device 510 family could be removed by specified removal device.

Item		Proposed device Hangzhou AGS MedTech Co., Ltd.	Predicate device （K172727） Hangzhou AGS MedTech Co., Ltd.	Comparion
		For 510 series, the released clip could be removed by specified instruments. 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.	was discharged through the intestine and anus	
	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	165cm, 195cm, 230cm	165cm, 195cm, 230cm	Same.

Item		Proposed device Hangzhou AGS MedTech Co., Ltd.	Predicate device （K172727） Hangzhou AGS MedTech Co., Ltd.	Comparion
	Removable performance	Yes	No such performance	Different, our proposed 510 Family add removable performance. Bench tests have been done for proposed device
Biological	**Metallic materials contacting with human body**	Clip part: SUS631, SUS304 Spring end: SUS303; Spring Tube: SUS304; Plastic Coated Spring Tube: SUS304, PE	Clip part: SUS631, SUS303 Connected end: SUS 303 Spring Tube: SUS304; Plastic Coated Spring Tube: SUS304, PE	Similar Different. Biocompatibility tests have been done for the difference. Biological risks are acceptable.
	Biocompatibility	ISO 10993-5:2009, ISO 10993-10:2010, ISO 10993-11:2017, ISO 10993-3:2014 ISO 10993-6:2016	ISO 10993-5:2009，ISO 10993-10:2010 ISO10993-11:2006，ISO 10993-3:2014	Similar Standard update

5.7 Applicable Guidance Document

NA

5.8 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.

Following tests was conducted in our non-clinical bench test:

Clip Releasing Force,
Open and Close,
Clamping Strength,
Tensile Strength,
Separation Force,
Rotation property,
Matching with Endoscope,
Removability Performance.

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 devices.