April 16, 2018

Hangzhou AGS MedTech CO., Ltd
℅ Ethan Liu
RA Specialist
Shanghai Thinkwell Consulting Co., Ltd.
Xinling Rd., 211/6F
Shanghai, 201100
China

Re: K172727
Trade/Device Name: Hemoclip
Regulation Number: 21 CFR§ 876.4400
Regulation Name: Hemorrhoidal Ligator
Regulatory Class: II
Product Code: PKL
Dated: March 5, 2018
Received: March 8, 2018

Dear Ethan Liu:

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Benjamin R. Fisher -S

Benjamin R. Fisher, Ph.D.
Director
Division of Reproductive, Gastro-Renal,
and Urological Devices
Office of Device Evaluation
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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K172727

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 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.

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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

This summary of 510(k) safety and effectiveness information is being submitted in accordance with requirements of 21 CFR Part 807.92.

5.1 Submitter

Submitted by:	Hangzhou AGS MedTech CO., Ltd. Building 6, Kangxin Road No.597, Qianjiang Economic Development Area , Hangzhou , Zhejiang , 311106, China
Establishment Registration Number:	Active; Awaiting Assignment Of Registration Number
Owner/Operator Number:	10052959
Contact Person:	Ethan Liu Phone:0086-15216699240 Fax: 0086-21-60732022 Email:xtdeepwater@126.com
Date Prepared:	Jan 18, 2017

5.2 Proposed Device

Trade Name:	Hemoclip
Common Name:	Endoscope Clipping Device
Classification:	Class II
Regulation Number	876.4400
Classification Name:	Hemorrhoidal ligator
Product Code Description:	Hemostatic Metal Clip For The Gi Tract
Product Code:	PKL

5.3 Predicate Device

K122660 - Resolution™ Hemostasis Clipping Device(Primary)

K161463- SureClip(TM) Repositionable Hemostasis Clip(Secondary)

5.4 Device Description

The Hemoclip is a sterile device consisting of a pre-loaded, radiopaque, single-use, endoscopic clipping device consisting of two main components: the delivery system and the clip. The delivery system consists of a handle and delivery catheter. 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 2300mm working lengths.

The clip consists of a stainless steel capsule, and clip arms, a Cobalt Chrome Yoke, and a styrene tension breaker. 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.

5.5 Indication 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 for GI tract luminal perforations<20mm that can be treated conservatively.

5.6 Comparison of Technology Characteristics

The Hemoclip has substantially equivalent device material, design, configuration, packaging fundamental technology, manufacturing process, sterilization process and intended use as those featured in the predicate device Resolution™ Hemostasis Clipping Device, Boston Scientific Corporation, K122660. And the Hemoclip has similar characteristics in Clip Opening Width, Working Length, and Rotation with SureClip™ Repositionable Hemostasis Clip, Micro-Tech(Nanjing) Co., Ltd, K161463.

Below is a table describing the differences and similarities of the Hemoclip in comparison to the Resolution™ Hemostasis Clipping Device and the SureClip™ Repositionable Hemostasis Clip.

Device & Predicate Devices	K172727	K122660	K161463
Indications for use	The hemoclip is indicated for use endoscopic clip placement within the gastrointestinal tract for the purpose of: 1. Endoscopic marking 2. Hemostasis for; - mucosal/sub-mucosal defects <3 cm - bleeding ulcers - arteries < 2cm - 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 supplemental closure method of luminal perforations <20mm that can be treated conservatively.	The resolution(tm) hemostasis clipping device is indicated for use endoscopic clip placement within the gastrointestinal tract for the purpose of: 1. Endoscopic marking 2. Hemostasis for; - mucosal/sub-mucosal defects <3 cm - bleeding ulcers - arteries < 2cm - 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 supplemental closure method of luminal	The SureClip(TM) Repositionable Hemostasis Clip is indicated for endoscopic clip placement within the gastrointestinal tract for the purpose of: (1) endoscopic marking, (2) hemostasis for (a) mucosal / sub-mucosal defects < 3cm, (b) bleeding ulcers, (c) polyps < 1.5cm in diameter, (d) diverticula in the colon, (3) as a supplementary method, closure of GI tract luminal perforations <20mm that can be treated conservatively

		perforations <20mm that can be treated conservatively	
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.	Endoscopic accessory used to deliver metal clips to the GI tract.
Repositionable Clip?	Yes and No (depending on model)	Yes	Yes
Minimum Endoscopic Working Channel	2.8 mm	2.8 mm	2.8 mm
Working Length	1650 mm, 1950 mm, 2350 mm,	1550 mm and 2350 mm	1650mm, 1950mm, 2350mm, 2700mm
Outer Tube Diameter	2.6 mm	2.6 mm	2.6 mm
Clip Opening Width	9 mm, 11 mm, 13 mm	11 mm	8mm, 11mm, 16mm
Sterilization method	EO	EO	EO
Clip Materials	Stainless Steel (SUS631)	304 Stainless Steel	SUS 631, SUS316, and SUS304 (Stainless steels)

5.7 Applicable Guidance Document

NA

5.8 Performance Data

The proposed device meets the requirements of ISO 10993 "Biological Evaluation of Medical Devices - Part 1: Evaluation and Testing", ISO 11135-1 "Sterilization of Health Care products Ethylene Oxide - Part 1: Requirements for Development, Validation, and Routine Control of Sterilization processes for Medical Devices", and ISO 10993-7 "Biological evaluation of medical devices - Part 7: ethylene oxide sterilization residuals"

The following bench tests were performed on Hemoclip: Open and Close, Clip releasing force, Clamping strength, Tensile Strength, Seperation Force, Rotation property, Corrosion, Appearance, Size. The results of all testing were passing.

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 Boston Scientific Corporation's currently marketed Resolution™ Hemostasis Clipping Device, K122660 and SureClip(TM) Repositionable Hemostasis Clip, Micro-Tech(Nanjing) Co., Ltd, K161463.