July 31, 2023

Yangzhou Fartley Medical Instrument Technology Co., Ltd.
℅ Ethan Liu
RA Speciialist
Shanghai Thinkwell Consulting Co., Ltd
Room 211/6F, Xinling Road, Minhang District
Shanghai, Shanghai 201100
China

Re: K230004
Trade/Device Name: Disposable Hemoclip
Regulation Number: 21 CFR§ 876.4400
Regulation Name: Hemorrhoidal Ligator
Regulatory Class: II
Product Code: PKL
Dated: June 29, 2023
Received: June 30, 2023

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. 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 -S

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)*
K230004

Device Name
Disposable Hemoclip

Indications for Use *(Describe)*
The Disposable 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.

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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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:	Yangzhou Fartley Medical Instrument Technology Co., Ltd. Address:Beizhou Road, Lidian Town, Guangling District, Yangzhou 225106 Jiangsu, China
Contact Person:	Ethan Liu RA Specialist Shanghai Thinkwell Consulting Co., Ltd Address: Room 211/6F, Xinling Road, Minhang Districtt, Shanghai, China. Phone: 0086-15216699240 Email: xtdeepwater@126.com
Date Prepared:	June 26, 2023

5.2 Device

Device Name:	Disposable Hemoclip
Classification Name:	Hemostatic Metal Clip For The Gi Tract
Regulatory Class:	II
Regulation Number:	21 CFR 876.4400
Regulation Name：	Hemorrhoidal ligator
Product Code:	PKL

5.3 Predicate Device

Device Name:	Hemoclip K172727
Manufacturer:	Hangzhou AGS MedTech Co., Ltd.
Classification Name:	Hemostatic Metal Clip For The Gi Tract
Regulatory Class:	II
Regulation Number:	21 CFR 876.4400
Regulation Name：	Hemorrhoidal ligator
Product Code:	PKL

5.4 Device Description

The Disposable Hemoclip consists of one pre-loaded clip and delivery system for single patient use only. Disposable Hemoclip is provided in sterile.

The clip is made of stainless steel with good superelasticity performance.The clip is

pre-loaded in end of the Spring tube part through its deformation and it is deployed from the delivery system during use.The clip is engineered such that they can be opened and closed up to many 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.
The delivery system consists of a handle and delivery catheter. The delivery system will allow for the device to rotate at the distal end.

5.5 Indication for Use:
The Disposable 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 Technological Characteristics
The Disposable Hemoclip has substantially equivalent device design, configuration, packaging fundamental technology, sterilization process and intended use as those featured in the predicate device Hangzhou AGS MedTech Co., Ltd.'s Hemoclip, K172727. The differences between the proposed device and the predicate devices do not raise any questions regarding its safety and effectiveness. The differences are listed in the table below.

Item	Disposable Hemoclip(**Proposed Device**)	Hemoclip K172727	Discussion
Indication for Use	The Disposable 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	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	Same

Item	Disposable Hemoclip(**Proposed Device**)	Hemoclip K172727	Discussion
	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.	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.	
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.	Same
Minimum Endoscopic Working Channel	2.8mm	2.8mm	Same
Working Length	1600mm, 1800mm, 2300mm, 2700mm	1650mm, 1950mm, 2350mm	Similar
Clip Opening Width	9mm,12mm, 16mm	9mm,11mm, 13mm	Similar
Outer Tube Diameter	2.5mm	2.6mm	Similar
SAL	10^{-6}	10^{-6}	Same
Sterilization Method	EO Sterilization	EO Sterilization	Same

5.7 Non-clinical 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 Disposable Hemoclip: Appearance, Size,

Hardness, Surface Roughness, Open and close performance, Rotation performance, Releasing force, Clipping force, Peeling force, Connection firmness, Dimensional Verification and MR Safety Testing. The results of all testing were passing.

5.8 Clinical Test Data

No Clinical Study is included in this submission.

5.9 Conclusion

In accordance with the Federal Food, Drug and Cosmetic Act, 21 CFR Part 807, Based on the information provided in this premarket notification, Yangzhou Fartley Medical Instrument Technology Co., Ltd. has demonstrated that proposed device Disposable Hemoclip is substantially equivalent to predicate device Hangzhou AGS MedTech Co., Ltd.'s currently marketed Hemoclip K172727 in terms of safety and effectiveness.