January 11, 2024

Alton (Shanghai) Medical Instruments Co. Ltd
Wei Song
Project Engineer
No.24 Building Jinshao Rd.1688.
Baoshan District.
200949 Shanghai
China

Re: K231633
Trade/Device Name: Disposable Hemoclip (AF series)
Regulation Number: 21 CFR 876.4400
Regulation Name: Hemorrhoidal Ligator
Regulatory Class: Class II
Product Code: PKL
Dated: December 11, 2023
Received: December 11, 2023

Dear Wei Song:

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 System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 systems (QS) regulation (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.

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: 06/30/2023
See PRA Statement below.

Submission Number *(if known)*

K231633

Device Name

Disposable Hemoclip (AF series)

Indications for Use *(Describe)*

The Disposable Hemoclip is indicated for clip placement within the gastrointestinal (GI) tract for the purpose of:
1. Endoscopic marking
2. Hemostasis for:
• Mucosal/sub-mucosal defects < 3 cm
• Bleeding ulcers
• Arteries < 2 mm
• Polyps < 1.5 cm 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 < 20 mm 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

I. SUBMITTER

Name: Alton (Shanghai) Medical Instruments Co. Ltd.

Address: No.24 Building, JinShao Rd. 1688, Baoshan District, 200949 Shanghai, P. R. China

Name of contact person: Vivian Li

Position: Director of Quality Department

Tel: +86 21 56771811

Fax: +86 21 66307823

Mail: vivian@alton.com.cn

Date prepared: 2024-01-11

II. Identification of Subjective Device

Device trade name: Disposable Hemoclip

Regulation Name: Hemorrhoidal Ligator

Regulation number: 21CFR 876.4400

Regulation class: 2

Review Panel: Gastroenterology/Urology

Product code: PKL

III. Identification of Predicate device

Predicate Submission Number: K172727

Trade/Device Name: Hemoclip

Regulation Name: Hemorrhoidal Ligator

Regulation Number: 21 CFR 876.4400

Regulatory Class: 2

Review Panel: Gastroenterology/Urology

Product Code Description: Hemostatic Metal Clip For The Gi Tract

Product Code: PKL

IV. Device description

The Disposable Hemoclip is the key and common accessory in the diagnosis and treatment procedure of digestive endoscope. As a single use instrument, the disposable hemoclip does not allow to be used by twice, and cannot be separated by components except to be used as well. It is also 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 tube. 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 1600mm, 1800mm, 2100mm and 2300mm working lengths.

The clip is made of stainless-steel material and deployed from the delivery system during use. The clip jaws are designed 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.

V. Indication for use

The Disposable Hemoclip is indicated for clip placement within the gastrointestinal (GI) tract for the purpose of:

1. Endoscopic marking

2. Hemostasis for:

• Mucosal/sub-mucosal defects < 3 cm

• Bleeding ulcers

• Arteries < 2 mm

• Polyps < 1.5 cm 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 < 20 mm that can be treated conservatively.

Precaution: It is recommended that healthcare providers distribute patient implant

cards with the name of the clip and date it was placed.

VI. Comparison of technological characteristics with the predicate device

Attribute	Subject device	Predicative device (K172727)	Discussion/ Conclusion
Trade name	Disposable Hemoclip (AF series)	Hemoclip	/
Manufacturer	Alton (Shanghai) Medical Instruments Co. Ltd	Hangzhou AGS MedTech CO., Ltd	/
Regulation name	Hemorrhoidal Ligator	Hemorrhoidal Ligator	Same
Regulatory Class	II	II	Same
Product code	PKL	PKL	Same
Clinical characteristics			
Indications for use	The Disposable Hemoclip is indicated for clip placement within the gastrointestinal (GI) tract for the purpose of: 1. Endoscopic marking 2. Hemostasis for: • Mucosal/sub-mucosal defects < 3 cm • Bleeding ulcers • Arteries < 2 mm • Polyps < 1.5 cm 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 < 20 mm that can be treated conservatively	The hemoclip is indicated for endoscopic clip placement within the gastrointestinal tract for the purpose of: 1. Endoscopicmarking 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.	Same
General technological characteristics			
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
Rotation function	360 ° rotatable	360 ° rotatable	Same
Reposition function	Yes	Yes and No (depending on model)	Same
Minimum Endoscopic Working Channel	Φ2.8mm	Φ2.8mm	Same
Outer Diameter of the clip	Φ2.4mm; Φ2.6mm	Φ2.6mm	Difference, see Discussion

Attribute	Subject device	Predicative device (K172727)	Discussion/ Conclusion
			1
Working Length	1600 mm, 1800 mm, 2100 mm, 2300 mm	1650 mm, 1950 mm, 2350 mm	Difference, see Discussion 2
Clip Opening Width	9 mm, 11 mm, 14 mm, 17 mm	9 mm, 11 mm, 13 mm	Difference, See Discussion 3
Clip material	Stainless Steel (SUS631)	Stainless Steel (SUS631)	Same
Sterilization	Method: Ethylene Oxide sterilization SAL: 10^{-6}	Method: Ethylene Oxide sterilization SAL: 10^{-6}	Same
Single use/reuse	For single use	For single use	Same
Mechanical performance	Surface roughness/Surface hardness/Clip Assembly Repeated Open/Close performance/Clip retention force/Clip releasing force/360º rotation performance/Clamp Close Force/Clamp strength-stability/Separation Force/Clip approach/Metal part against corrosion	Open and Close/Clip releasing force/Clamping strength/Tensile Strength/Separation Force/ Rotation property/Corrosion	Difference, See Discussion 4
Biocompatibility	FDA guidance and ISO 10993-1 “Biological Evaluation of Medical Devices − Part 1: Evaluation and Testing Within a Risk Management Process”	ISO 10993 "Biological Evaluation of Medical Devices - Part 1: Evaluation and Testing"	Same
MR Environment	MR Unsafe	Unknown	Difference, See Discussion 5

Discussion on differences between the subject device and the predicate device

Discussion 1: There are two specifications (Φ2.4mm; Φ2.6mm) related to outer diameter of the clip for the subject device. Φ2.6mm specification is same as the predicate device. Φ2.4mm specification is applicable for smaller endoscopic working channel, different from the predicate device. As the size of the outer diameter is designed to be compatible with the smaller size of the endoscopic working channel during the surgical procedure, in addition, the Φ2.4mm specification has been

available on the other marketed device (K213338). Therefore, such differences will not affect clinical performance and safety of the subject device.

Discussion 2: The working length specification of the subject device is different from ones of the predicate device. The different working length designed is applicable for different endoscope length to reach the location of the lesion or the location as the operator expected, and the maximum working length of the subject device is shorter than the maximum one of the predicate device, therefore, such differences will not affect clinical performance and safety of the subject device.

Discussion 3: There are slightly different and more optional specifications of clip opening width on the subject device than the predicate device. The different opening width is designed appropriately for closure of tissues with different thickness and there are many optional specification available on the legally marketed devices, like 22 mm specification is available on Lockado™ Repositionable Hemostasis Clip (K202333). In addition, mechanical performance regarding the clamp between the subject device and the predicate device has been performed and the test results demonstrate substantial equivalence between the subject device and the predicate device. Therefore, such differences will not affect clinical performance and safety of the subject device.

Discussion 4: The bench performance tests, including mechanical performance, were carried out on both the subject device and the predicate device according to specific product technical specification and the test results demonstrate substantial equivalence between the subject device and the predicate device. therefore, such difference will not affect effectiveness and safety of the subject device.

Discussion 5: The disposable hemoclip is MR Unsafe. And the MR Environment for the predicate device is unknown. As warning related to MR Unsafe has been added in the IFU to protect the devices from use in MR environment, such difference will not affect effectiveness and safety of the subject device.

VII. Summary of substantial equivalence discussion

Based on the above comparison table as well as discussion on differences, the subject device and the predicate device have similar design features and performance

specifications. Although there are some differences on size specification parameters (e.g. applicable endoscopic working channel, working length, outer diameter of the clip and clip opening width) on the subject device and predicate device, such differences will not affect the effectiveness and safety of the subject device. In addition, a performance comparison testing between the subject device and the predicate device is implemented and all performances including mechanical property are verified to confirm the performance of the subject device is substantially equivalent to the predicate device. These technological differences between the subject device and the predicate device do not affect the safety and effectiveness of the subject device when used as labeled.

VIII. Summary of Non-clinical Data

Non-clinical testing for Disposable Hemoclip was conducted to verify that the subject device met all design specifications, demonstrated safety and essential performance based on current applicable standards, and to demonstrate substantial equivalence to the predicate. The following tests were performed.

- Biocompatibility

The biocompatibility evaluation for the Disposable Hemoclip was conducted in accordance with the FDA guidance "Use of International Standard ISO 10993-1, 'Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process'" September 4, 2020, and International Standard ISO 10993-1 "Biological Evaluation of Medical Devices − Part 1: Evaluation and Testing Within a Risk Management Process," as recognized by FDA.

Clip part of the Disposable Hemoclip is released during the operation and will be retained and directly in contact with patient's tissue for a prolong contact duration (> 24 hours to 30 days), therefore, the following tests are considered and passed:

- MTT Cytotoxicity Test: ISO 10993-5:2009, Biological evaluation of medical devices -- Part 5: Tests for In Vitro cytotoxicity
- Skin Sensitization Test, Intracutaneous Test: ISO 10993-10:2010, Biological evaluation of medical devices -- Part 10: Tests for irritation and sensitization
- Acute Systemic Toxicity Test, Subacute Systemic Toxicity Test, Subchronic

Systemic Toxicity Test and Pyrogen Test: ISO 10993-11:2017 Biological evaluation of medical devices - Part 11: Tests for systemic toxicity

- Genotoxicity Test: ISO 10993-3:2014 Biological evaluation of medical devices - Part 3: Tests for genotoxicity, carcinogenicity and reproductive toxicity
- Muscle Implant Test: ISO 10993-6: 2016 Biological evaluation of medical devices - Part 6: Tests for local effects after implantation

➢ Sterilization Validation

The EO sterilization of the Disposable Hemoclip has been validated according to the following applicable standards:

- ISO11135:2014+A1:2018 Sterilization of medical device- validation and routine control of ethylene oxide sterilization
- ISO 11737-2:2019 Sterilization of Medical Device-Microbiological methods-part 2: Tests of sterility performed in the validation of a sterilization process
- ISO 10993-7:2008 Biological evaluation of medical devices - Part 7: Ethylene oxide sterilization residuals
- USP <85> Bacterial endotoxins test

➢ Shelf Life and Sterile Barrier System

Shelf Life and Sterile Barrier System of the Disposable Hemoclip has been validated according to the following applicable standards:

- ASTM F1980-16 Standard Guide for Accelerated Aging of Sterile Barrier Systems for Medical Devices
- ISO11607-1:2019 Packaging for terminally sterilized Medical Device Part 1: Requirement for materials，sterile barrier systems and packaging systems
- ISO11607-2:2019 Packaging for terminally sterilized Medical Device Part 2: Validation Requirement for forming, sealing and assembly process
- ASTM F 1929-15: Standard Test Method for Detecting Seal Leaks in Porous Medical Packaging by Dye Penetration
- ASTM D 3078-02(2013): Standard Test Method for Determination of Leaks

in Flexible Packaging by Bubble Emission

- DIN 58593-6: 2016 Sterilization – Sterile Supply – Part 6: Microbial Barrier Testing of Packaging Materials for Medical Devices Which Are to Be Sterilized
- ASTM F88/F88M-15 Standard Test Method for Seal Strength of Flexible Barrier Materials
- ASTM D4169-16 Standard practice for performance testing of shipping containers and systems (DC-13, Level II)

➢ Performance Data – Bench

The performance tests were implemented on both the Disposable Hemoclip (subject device) and the predicate device (AGS Hemoclip) to demonstrate substantial equivalence according to the specific product specification with the following test items:

- Surface roughness & Surface hardness
- Clip Assembly Repeated Open/Close Performance
- Clip Retention Force
- Clip Releasing Force
- 360º Rotation performance
- Clip Close Force
- Clamp strength-durability
- Clamp strength-stability
- Separation Force
- Clip approach
- Metal Part Against Corrosion

➢ Performance Data – Animal

N/A, no animal studies are available for the subject device.

IX. Summary of Clinical Data

N/A, no clinical studies are available for the subject device.

X. Conclusions

In conclusion, the technological characteristics, features, specifications, materials,

principle of operation, and intended use of the subject device substantially equivalent to the predicate devices quoted above. The differences between the subjective device and its predicate device do not introduce a new intended use and do not raise new issues of safety and effectiveness. Verification and Validation testing demonstrated that no adverse effects have been introduced by these differences and that the device performs as intended. From the results of nonclinical testing described, it can be concluded that the subject device is substantially equivalent to the legally marketed predicate device.