July 12, 2024

Promisemed Hangzhou Meditech Co., Ltd.
Zearou Yang
Regulatory affairs manager
No. 1388 Cangxing Street, Cangqian Community,Yuhang District
Hangzhou City, Zhejiang 311121
China

Re: K234124
Trade/Device Name: Single Use Hemoclips
Regulation Number: 21 CFR 876.4400
Regulation Name: Hemorrhoidal Ligator
Regulatory Class: Class II
Product Code: PKL
Dated: December 28, 2023
Received: June 12, 2024

Dear Zearou Yang:

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: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K234124

Device Name

Single Use Hemoclips

Indications for Use *(Describe)*

The device is used for endoscopic clip placement within the gastrointestinal(GI) tract for the purpose of endoscopic marking, hemostasis for mucosal/submucosal defects less than 3cm, bleeding ulcers, arteries less than 2mm, polyps less than 1.5cm in diameter and diverticula in the colon. Anchoring to affix jejunal feeding tubes to the wall of the small bowel. Closure of GI tract lumenal perforations less than 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.

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510(k) Summary

Date prepared: 2024-07-12

1. Manufacturer ***[21 CFR 807.92 (a) (1)]***	
Name	Promisemed Hangzhou Meditech Co., Ltd.
Address	No. 1388 Cangxing Street, Cangqian Community, Yuhang District, Hangzhou City, 311121 Zhejiang, China.
Contact Person	Zearou Yang
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2. Device ***[21 CFR 807.92 (a) (2)]***	
Name	Single Use Hemoclips
Common Name	Single Use Hemoclips
Classification Name	Hemorrhoidal ligator
Regulation Number	876.4400
Class	Class II
Product Code	PKL
3. Legally Marketed Predicate Device ***[21 CFR 807.92 (a) (3)]***	
Predicate Name	Hemoclip
510(k) Number	K211787
Product Code	PKL
Reference Devices	No reference devices were used in this submission.
4. Device Description ***[21 CFR 807.92 (a) (4)]***	
The Single Use Hemoclip is a sterile, single use device that consists of metal clip that detaches from the introducer to maintain approximation of tissue to achieve hemostasis and endoscopic marking in the gastrointestinal tract. The device is provided sterile (EO).	

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The large clip opening design meets various clinical treatment demands. It can be opened and closed repeatedly and can achieve repositioning. The 360°rotatable design is convenient for clinical use.
It consists of two main components, delivery system and clip assembly. And it is offered in different dimensions.

5. Indication for use *[21 CFR 807.92 (a) (5)]*

The device is used for endoscopic clip placement within the gastrointestinal(GI) tract for the purpose of endoscopic marking, hemostasis for mucosal/submucosal defects less than 3cm, bleeding ulcers, arteries less than 2mm, polyps less than 1.5cm in diameter and diverticula in the colon. Anchoring to affix jejunal feeding tubes to the wall of the small bowel. Closure of GI tract lumenal perforations less than 20mm that can be treated conservatively.

6. Indications for Use Comparison *[21 CFR 807.92 (a) (5)]*

The subject device and predicate device indications for use statements are similar. See Section 7 below.

7. Comparison of Technological Characteristic *[21 CFR 807.92 (a) (6)]*

Compared with the predicate device, the subject device is identical in mechanism of action, materials, dimension, sterilization method and biocompatibility. The subject device has the same performance specifications except for working length. Through performance bench testing, the subject device and the predicate device demonstrated to be substantially equivalent. At a high level, the subject and predicate devices are based on the following same technological elements:

Specification	Subject Device	Predicate Device(K211787)	Discussion of difference
Trade Name	Single Use Hemoclips	Hemoclip	
Manufacturer	Promisemed Hangzhou Meditech Co., Ltd	Hangzhou AGS MedTech Co., Ltd.	
Device Class	Class II	Class II	No difference
Product Code	PKL	PKL	No difference
Regulation number	21 CFR 876.4400	21 CFR 876.4400	No difference
Prescription/over-the-counter use	Prescription	Prescription	No difference
Indications for Use	The device is used for endoscopic clip placement within the gastrointestinal(GI) tract for the purpose of endoscopic marking, hemostasis for mucosal/submucosal defects less than 3cm, bleeding ulcers, arteries less than 2mm, polyps less than 1.5cm in diameter and diverticula in the colon. Anchoring to affix jejunal feeding tubes to the wall of	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 < 2 mm, ● Polyps < 1.5cm in diameter, ● Diverticula in the colon, ● Prophylactic clipping to reduce the risk of	Similar

	the small bowel. Closure of GI tract lumenal perforations less than 20mm that can be treated conservatively.	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.	
Single Use	Yes	Yes	No difference
Material (direct/indirect contact body)			
Clip and pressure tube	X7CrNiAl17-7 (SUS 631), X10CrNiS18-9 (SUS303)	Stainless steel (SUS631, SUS304)	The use of SUS303 does not introduce any new concerns for safety or efficacy which has been confirmed performance and biocompatibility testing.
Springe tube	X7CrNi18-9 (SUS304)	X7CrNi18-9 (SUS304)	No difference
Components			
Configuration	Delivery system and clip part	Delivery system and clip part	No difference
Performance			
Open width	9mm, 12mm, 15mm	9mm, 11mm, 13mm, 16mm and 18mm	Open width of subject device is not beyond the predicate device scope and does not introduce any new concerns for safety or efficacy which has been confirmed performance testing.
Minimal working channel	2.8mm	2.8mm	No difference
Working length	1650mm, 1950 mm, 2300 mm, 2700mm.	1650mm, 1950mm, 2300mm	Working length of subject device is more longer the predicate device scope and does not introduce any new concerns for safety or efficacy which has been confirmed performance testing.

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Removability performance	Yes	Yes	No difference
Sterility (SAL of 10^{-6})	Yes	Yes	No difference
Sterilization method	Ethylene Oxide	Ethylene Oxide	No difference
Shelf life	3 years	3 years	No difference
Biocompatibility	ISO 10993-3:2014, ISO 10993-5:2009, ISO 10993-6:2016, ISO 10993-10:2021, ISO 10993-11:2017, ISO 10993-23:2021, USP <151>, 2017	ISO 10993-3:2014, ISO 10993-5:2009, ISO 10993-6:2016, ISO 10993-10:2010, ISO 10993-11:2017	The biocompatibility testing for subject device has been tested in accordance with the ISO 10993-1: 2018, and results are qualified.

8. Nonclinical test *[21 CFR 807.92 (b) (1)]*

The bench testing performed verifies that the performance of the subject device is substantially equivalent in terms of critical performance characteristics to the predicate device. These tests include:

- Appearance;
- Clip Releasing Force
- Open and Close;
- Clamping Strength;
- Tensile Strength;
- Separation Force;
- Rotation property;
- Matching with Endoscope;
- Removability Performance;
- Hemoclip assembly mechanical integrity;
- EO residual;
- Sterility;
- Package performance (Appearance, Sealing strength, Dye penetration);
- Biocompatibility was tested by the third GLP laboratory following ISO 10993-1:2018.

9. Clinical test *[21 CFR 807.92 (b) (2)]*

No clinical test is included in this submission.

10. Conclusion *[21 CFR 807.92 (b) (3)]*

Based on the information provided within this 510(k) submission, the subject device is substantially equivalent to the predicate device and is as safe, as effective and performs as well as the legally marketed predicate device.