September 8, 2025

Micro-Tech (Nanjing) Co., Ltd
Sally He
Regional RA Manager
No. 10 Gaoke Third Road,
Nanjing National Hi-Tech Industrial Development Zone
Nanjing, Jiangsu 210032
China

Re: K250229
Trade/Device Name: Dual Action Tissue Closure Device
Regulation Number: 21 CFR 876.4400
Regulation Name: Hemorrhoidal Ligator
Regulatory Class: Class II
Product Code: PKL
Dated: August 8, 2025
Received: August 8, 2025

Dear Sally He:

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.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

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,

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: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K250229

Device Name

Dual Action Tissue Closure Device

Indications for Use *(Describe)*

The Dual Action Tissue Closure Device is intended for use in flexible endoscopy for the compression of tissue in the gastrointestinal tract.
The Dual Action Tissue Closure Device is indicated for clip placement within the gastrointestinal tract for the purpose of:
- Endoscopic marking,
- Hemostasis for
  - Mucosal/sub-mucosal defects < 5 cm,
  - Bleeding ulcers,
  - Polyps < 1.5 cm in diameter,
  - Diverticula in the colon,
  - Arteries < 2 mm,
- As a supplementary method, closure of GI tract 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.

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510(k) Summary

This 510(k) Summary of 510(k) safety and effectiveness information is being submitted in accordance with requirements of SMDA 1990 and Title 21, CFR Section 807.92.

The assigned 510(k) Number: K250229

1. Date of Preparation: 2025-08-06

2. Sponsor Identification

Micro-Tech (Nanjing) Co., Ltd.

No.10 Gaoke Third Road, Nanjing National Hi-Tech, Industrial Development Zone, Nanjing, Jiangsu Province, PRC

Establishment Registration Number: 3004837686

Contact Person: Sally He

Position: Regional RA Manager

Tel: +86-25-58646378

Fax: +86-25-58350006

Email: ra.micro-tech@outlook.com

3. Identification of Proposed Device

Product Name: Dual Action Tissue Closure Device

Regulatory Information

Classification Name: Hemostatic Metal Clip For The GI Tract

Classification: 2

Product Code: PKL

Regulation Number: 876.4400

Review Panel: Gastroenterology/Urology

4. Identification of Predicate/Reference Device

Predicate Device:

510(k) Number: K233772

Product Name: Dual Action Tissue Closure Device

Manufacturer: Micro-Tech (Nanjing) Co., Ltd.

Reference Device:

510(k) Number: K202333

Product Name: Lockado™ Repositionable Hemostasis Clip

Manufacturer: Micro-Tech (Nanjing) Co., Ltd.

5. Indications for Use

The Dual Action Tissue Closure Device is intended for use in flexible endoscopy for the compression of tissue in the gastrointestinal tract.
The Dual Action Tissue Closure Device is indicated for clip placement within the gastrointestinal tract for the purpose of:

- Endoscopic marking,
- Hemostasis for
  - Mucosal/sub-mucosal defects < 5 cm,
  - Bleeding ulcers,
  - Polyps < 1.5 cm in diameter,
  - Diverticula in the colon,
  - Arteries < 2 mm,
- As a supplementary method, closure of GI tract luminal perforations < 20 mm that can be treated conservatively.

6. Device Description

The proposed device Dual Action Tissue Closure Device is a sterile, single-use endoscopic clipping device. The Dual Action Tissue Closure Device is intended for use in flexible endoscopy for the compression of tissue in the gastrointestinal tract for adult patient only. It consists of two main components, delivery system and clip component. The proposed devices are EO sterilized to achieve the Sterility Assurance Level (SAL) of 10^{-6} and placed in a sterility maintenance package to ensure a shelf

life of 1 year.

7. Comparison of Technological Characteristics

The Dual Action Tissue Closure Device incorporates substantially equivalent device's design, configuration, intended use, packaging fundamental technology, manufacturing processes including sterilization process as those featured in the predicate device **Disposable Dual Action Tissue Closure Device** cleared under K233772.

ITEM	**Proposed Device** Dual Action Tissue Closure Device	**Predicate Device** Disposable Dual Action Tissue Closure Device (K233772)	**Remark**
Product Code	PKL	PKL	SE
Regulation No.	876.4400	876.4400	SE
Class	2	2	SE
Indications for Use	The Dual Action Tissue Closure Device is intended for use in flexible endoscopy for the compression of tissue in the gastrointestinal tract. The Dual Action Tissue Closure Device is indicated for clip placement within the gastrointestinal tract for the purpose of: • Endoscopic marking, • Hemostasis for ○ Mucosal/sub-mucosal defects < 5 cm, ○ Bleeding ulcers, ○ Polyps < 1.5 cm in diameter, ○ Diverticula in the colon, ○ Arteries < 2 mm, • As a supplementary method,	The Disposable Dual Action Tissue Closure Device is intended for use in flexible endoscopy for the compression of tissue in the gastrointestinal tract. The Disposable Dual Action Tissue Closure Device is indicated for clip placement within the gastrointestinal tract for the purpose of: • Endoscopic marking, • Hemostasis for ○ Mucosal/sub-mucosal defects < 5 cm, ○ Bleeding ulcers, ○ Polyps < 1.5 cm in diameter, ○ Diverticula in the colon, ○ Arteries < 2 mm, • As a supplementary method,	SE

510(k) summary

ITEM	Proposed Device Dual Action Tissue Closure Device	Predicate Device Disposable Dual Action Tissue Closure Device (K233772)	Remark
	closure of GI tract luminal perforations < 20 mm that can be treated conservatively.	closure of GI tract luminal perforations < 20 mm that can be treated conservatively.	
Configuration	Two handles control the opening and closing of the two corresponding clips.	Two handles control the opening and closing of the two corresponding clips.	SE
Principles of Operation	Pull the steel wire through the operating handle to drive the opening and closing of the clip to clamp the tissue. It is a metallic device with a clasping mechanism.	Pull the steel wire through the operating handle to drive the opening and closing of the clip to clamp the tissue. It is a metallic device with a clasping mechanism.	SE
Open width L1 (mm)	9≤L1＜12 12≤L1＜15 15≤L1＜18	15±3	Different
Lateral Teeth	With /Without	Without	Different
Working Length (mm)	1650, 1950, 2350	1650, 1950, 2350	SE
Minimal working channel of endoscopy (mm)	2.8 mm	3.2 mm	Different
Supplied in Sterile	Yes	Yes	SE
Single Use	Yes	Yes	SE
Packaging	Single-use EO sterilized pouch with one device per pouch	Single-use EO sterilized pouch with one device per pouch	SE
Labeling	Conform to 21 CFR part 801	Conform to 21 CFR part 801	Same
Biocompatibility	Comply with ISO10993-1	Comply with ISO10993-1	SE
MRI	Comply with ASTM F 2503, ASTM F 2052, ASTM F2119, ASTM F2182, ASTM F2213	Comply with ASTM F 2503, ASTM F 2052, ASTM F2119, ASTM F2182, ASTM F2213	SE

8. Performance Data

The performances of Dual Action Tissue Closure Device are as follows:

- Dimension
- Clip Assembly Repeated Open/Close;
- Scope Compatibility/Usability;
- Endoscope Damage;
- Biopsy Valve compatibility;
- Clip approach;
- Clip Open and Close Force;
- Release Force;
- Tensile Strength;
- Clamping Strength;
- Roll Tube to handle Tensile.
- Mechanical Integrity of Clip Assembly
- Rotation performance
- Torque
- MRI Safety Evaluation

Compared with the predicate device Disposable Dual Action Tissue Closure Device cleared under K233772, the proposed devices have the same design, configuration, principles of operation, control mechanism as the predicate device, except the rotation performance and torque, all the others performances and performance specification are also the same as the predicate device (K233772). For the rotation performance and torque, the performances and performance specification are the same as the reference device (K202333).

Shelf-life testing was conducted based on an accelerated aging test in accordance with ASTM F1980-21 Standard Guide for Accelerated Aging of Sterile Barrier Systems for Medical Devices. The shelf life of proposed device is one year.

Sterilization validation was carried out in accordance with ISO 11135:2014 “Sterilization of Health Care products - Ethylene Oxide - Part 1: Requirements for Development, Validation, and Routine Control of Sterilization processes for Medical Devices”.

MR compatibility was evaluated in accordance with ASTM F 2503, ASTM F 2052, ASTM F2119, ASTM F2182, ASTM F2213 and FDA guidance on Testing and Labeling Medical Devices for Safety in the Magnetic Resonance (MR) Environment issued on May 20, 2021.

9. Animal Study

No animal study is included in this submission.

10. Clinical Study

No clinical study is included in this submission.

11. Substantially Equivalent (SE) Conclusion

Based on the indications for use, technological characteristics, safety and performance testing, **Dual Action Tissue Closure Device** has been shown to be appropriate for its intended use and is considered to be substantially equivalent to the currently cleared predicate device **Disposable Dual Action Tissue Closure Device** cleared under K233772.