March 19, 2024

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: K233772
Trade/Device Name: Disposable Dual Action Tissue Closure Device
Regulation Number: 21 CFR 876.4400
Regulation Name: Hemorrhoidal Ligator
Regulatory Class: Class II
Product Code: PKL
Dated: January 19, 2024
Received: January 19, 2024

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.

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.

510(k) Number *(if known)*
K233772

Device Name
Disposable Dual Action Tissue Closure Device

Indications for Use *(Describe)*
The Disposable 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.

The Disposable Dual Action Tissue Closure Device is indicated for clip placement within the gastrointestinal tract for the purpose of:
1. Endoscopic marking;
2. Hemostasis for:
a.Mucosal/sub-mucosal defects < 5 cm,
b.Bleeding ulcers,
c.Polyps < 1.5 cm in diameter,
d.Diverticula in the colon,
e.Arteries < 2 mm,
3. 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.

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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: K233772

1. Date of Preparation: 2024-03-14

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

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3. Identification of Proposed Device

Trade Name: Disposable Dual Action Tissue Closure Device

Common Name: Hemostasis Clip

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 Device

510(k) Number: K212748

Product Name: Disposable Dual Action Tissue Clip

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

5. Indications for Use

The Disposable 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.

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, closure of GI tract luminal perforations < 20 mm that can be treated conservatively.

6. Device Description

The proposed device Disposable Dual Action Tissue Closure Device is a sterile, single-use endoscopic clipping device, intended to be used in flexible endoscopy for the compression, manipulation of tissue in the gastrointestinal tract. It consists of two main components, delivery system and clip assembly. 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 3 years.

7. Comparison of Technological Characteristics

The Disposable Dual Action Tissue Closure Device incorporates substantially equivalent device's

materials, design, configuration, packaging fundamental technology, manufacturing processes including sterilization process as those featured in the predicate device **Disposable Dual Action Tissue Clip** cleared under K212748.

ITEM	**Proposed Device** Disposable Dual Action Tissue Closure Device	**Predicate Device** Disposable Dual Action Tissue Clip (K212748)	**Remark**
Product Code	PKL	PKL	Same
Regulation No.	876.4400	876.4400	Same
Class	2	2	Same
Indications for Use	The Disposable 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. 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, closure of GI tract luminal perforations < 20 mm that can be treated conservatively.	The Disposable 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. 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 < 3 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.	One indication is changed
Configuration	2 delivery units of the delivery system and 2 separate clips of the clip assembly	2 delivery units of the delivery system and 2 separate clips of the clip assembly	Same
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	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	Same

510(k) summary

ITEM	**Proposed Device** Disposable Dual Action Tissue Closure Device	**Predicate Device** Disposable Dual Action Tissue Clip (K212748)	**Remark**
	device with a clasping mechanism.	device with a clasping mechanism.	
Open width (mm)	15	15	Same
Working Length (mm)	1650,1950,2350	1650,1950,2350	Same
Minimal working channel of endoscopy (mm)	3.2	3.2	Same
Supplied in Sterile	Yes	Yes	Same
Single Use	Yes	Yes	Same
Packaging	Single-use EO sterilized pouch with one device per pouch	Single-use EO sterilized pouch with one device per pouch	Same
Shelf Life	Three years	One year	Different
Biocompatibility	Conform to ISO 10993-1	Conform to ISO 10993-1	Same
Sterilization	EO Sterilized, SAL:10^{-6}	EO Sterilized, SAL:10^{-6}	Same
Labeling	Conform to 21 CFR part 801	Conform to 21 CFR part 801	Same
MRI information	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	Same

8. Performance Data

The performances of Disposable 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;
- Coil to handle Tensile.
- Mechanical Integrity of Clip Assembly

Compared with the predicate device Disposable Dual Action Tissue Clip cleared under K212748, the proposed devices have the same design, dimension, configuration, material, principles of operation, control mechanism as the predicate device, the performances and performance specification are also the same as the predicate device, no change. The performance of proposed device is substantially equivalent to the predicate devices **Disposable Dual Action Tissue Clip (K212748).**

The bench performance testing that was previously conducted on the predicate device and not re-conducted on the proposed device.

Shelf-life testing was conducted based on an accelerated aging test in accordance with ASTM F1980-16 Standard Guide for Accelerated Aging of Sterile Barrier Systems for Medical Devices. Compared with the predicate device, the shelf life was changed to three years. Three-years accelerated aging tests were performed using the same test method and acceptance criteria as predicate device to demonstrate the stability and support the results of the accelerated aging test.

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”. Compared with the predicate device, the sterilization method is not changed. The sterilization validation testing that was previously conducted on the predicate device and not re-conducted on the proposed device.

Compared with the predicate device, the material of proposed device is not changed, therefore, the biocompatibility of proposed device is also the same. The tests that were submitted for the predicate

device are as followed:

a) Cytotoxicity

b) Sensitization

c) lntracutaneous Reactivity

d) Acute Systemic Toxicity

e) Material Mediated Pyrogenicity

f) Chemical Characterization

The biocompatibility performance testing that was previously conducted on the predicate device and not re-conducted on the proposed device.

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. Compared with the predicate device, the material and MR environment of proposed device are not changed. The MR compatibility performance testing that was previously conducted on the predicate device and not re-conducted on the proposed device.

For the indication change, clinical literature was used to support changing the IFU to include hemostasis for mucosal/sub-mucosal defects up to 5 cm.

For the shelf life change, shelf-life testing was conducted to support a longer shelf-life of 3 years.

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,

Disposable 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 Clip** cleared under K212748.