January 20, 2022

Micro-Tech (Nanjing) Co., Ltd.
Cecilia Sun
RA Engineer
No.10 Gaoke Third Road, Nanjing National Hi-Tech
Industrial Developement Zone
Nanjing, Jiangsu Province 210032
CHINA

Re: K212748
Trade/Device Name: Disposable Dual Action Tissue Clip
Regulation Number: 21 CFR 876.4400
Regulation Name: Hemorrhoidal ligator
Regulatory Class: Class II
Product Code: PKL,
Dated: December 3, 2021
Received: December 20, 2021

Dear Cecilia Sun:

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,

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.

510(k) Number *(if known)*

K212748

Device Name
Disposable Dual Action Tissue Clip

Indications for Use *(Describe)*

The Disposable Dual Action Tissue Clip 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 Clip 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.

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: **K212748**

1. **Date of Preparation: 2021-12-03**

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: Cecilia Sun

Position: RA Engineer

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Fax: +86-25-58350006

Email: RA.Micro-Tech@outlook.com

3. **Identification of Proposed Device**

Trade Name: Disposable Dual Action Tissue Clip

Common Name: Hemostasis Clip

Regulatory Information

Classification Name: Hemostatic Metal Clip For The GI Tract

Classification: II

Product Code: PKL

Regulation Number: 876.4400

Review Panel: Gastroenterology/Urology

4. Identification of Predicate Device

Predicate Device

510(k) Number: K202333

Product Name: Lockado™ Repositionable Hemostasis Clip

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

5. Indications for Use

The Disposable Dual Action Tissue Clip 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 Clip 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.

6. Device Description

The proposed device Disposable Dual Action Tissue Clip is a sterile, single-use endoscopic clipping device, intended to be used in flexible endoscopy for the compression 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 1 year.

7. Comparison of Technological Characteristics

The Disposable Dual Action Tissue Clip incorporates substantially equivalent device materials, design, configuration, packaging fundamental technology, manufacturing processes, sterilization process and intended use as those featured in the predicate device **Lockado™ Repositionable Hemostasis Clip** cleared under K202333.

Table 7.1 Comparison to predicate Devices

Item	**Proposed Device** Disposable Dual Action Tissue Clip	**Predicate Device** Lockado™ Repositionable Hemostasis Clip (K202333)	**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 Clip 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 Clip 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.	The Lockado™ Repositionable Hemostasis Clip is indicated for Endoscopic clip placement within the Gastrointestinal tract in adult populations only via a straight or side viewing flexible endoscope for the purpose of : (1) Endoscopic marking; (2) Hemostasis for (a) Mucosal / sub-mucosal defects < 3cm, (b) Bleeding ulcers, (c) polyps < 1.5cm in diameter, (d) diverticula in the colon, (e) Arteries < 2 mm,` (f) Prophylactic clipping to reduce the risk of delayed bleeding post lesion resection. (3) as a supplementary method, closure of GI tract luminal perforations <20mm that can be treated conservatively. (4) Anchoring to affix jejunal	Covered by the predicated device

Item	**Proposed Device** Disposable Dual Action Tissue Clip	**Predicate Device** Lockado™ Repositionable Hemostasis Clip (K202333)	**Remark**
		feeding tubes to the wall of the small bowel;	
Configuration	2 delivery units of the delivery system and 2 separate clips of the clip assembly	Delivery system and clip assembly	Similar
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.	Same
Open width (mm)	15	8,11,16,22	Similar
Working Length (mm)	1650,1950,2350	1650,1950,2350,2700	Similar
Minimal working channel of endoscopy (mm)	3.2	2.8	Different
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	One year	Two years	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

Performance testing was conducted to demonstrate the essential performance of the proposed device **Disposable Dual Action Tissue Clip** and confirmed that the proposed device works as intended with the compatible devices.

The bench tests below were tested and evaluated as substantially equivalent to the predicate device.

- Dimension;
- Release Force;
- Clamping Strength;
- Tensile Strength;
- Clip Assembly Repeated Open/Close;
- Clip Open And Close Force
- Scope Compatibility/Usability;
- Endoscope Damage;
- Biopsy Valve Compatibility;
- Clip Approach;
- Coil to Handle Tensile
- Mechanical integrity of Clip Assembly Test

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. Two-year aging test will be performed to demonstrate longer 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”.

Biocompatibility testing was performed 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".

MR compatibility was evaluated in accordance with ASTM F 2503, ASTM F 2052, ASTM F2119, ASTM F2182, ASTM F2213 and FDA guidance "Establishing Safety and Compatibility of Passive Implants 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, and safety and performance testing, the **Disposable Dual Action Tissue Clip** has been shown to be appropriate for its intended use and is considered to be substantially equivalent to the currently cleared predicate device **Lockado™ Repositionable Hemostasis Clip** cleared under K202333.