June 13, 2022

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

Re: K220157
Trade/Device Name: Disposable Hemostatic Closure Clip Device
Regulation Number: 21 CFR 876.4400
Regulation Name: Hemorrhoidal ligator
Regulatory Class: Class II
Product Code: PKL
Dated: May 11, 2022
Received: May 13, 2022

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 (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,

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)*
K220157

Device Name
Disposable Hemostatic Closure Clip Device

Indications for Use *(Describe)*
The device for flexible endoscopy and for compression of tissue in the gastrointestinal (GI) tract, for hemostasis or for treating gastrointestinal organ wall lesions, and for making of lesions. The Device is indicated for clip placement within the GI tract for the purpose of:
a .Endoscopic Marking
b. Hemostasis for:
- Mucosal/Submucosal defects < 3cm
- Bleeding Ulcers
- Arteries <2 mm
- Polyps < 1.5 cm in diameter
- Diverticula in the Colon
c. Closure of GI tract luminal perforations < 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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510K 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: **K220157**

1. **Date of Preparation: 2022-05-10**

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
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3. **Identification of Proposed Device**

Product Name: Disposable Hemostatic Closure Clip Device
Trade Name: /
Common Name: Hemostasis Clip
Regulatory Information
Classification Name: Hemorrhoidal ligator
Classification: 2
Product Code: PKL
Regulation Number: 876.4400
Review Panel: Gastroenterology/Urology

4. Identification of Predicate Device

510(k) Number: K101428

Product Name: OTSC™ (over-the scope-clip) system set

Manufacturer: Ovesco Endoscopy AG

5. Indications for Use

The device for flexible endoscopy and for compression of tissue in the gastrointestinal (GI) tract, for hemostasis or for treating gastrointestinal organ wall lesions, and for making of lesions. The Device is indicated for clip placement within the GI tract for the purpose of:

a .Endoscopic Marking

b. Hemostasis for:

- Mucosal/Submucosal defects < 3cm
- Bleeding Ulcers
- Arteries < 2 mm
- Polyps < 1.5 cm in diameter
- Diverticula in the Colon

c. Closure of GI tract luminal perforations < 20mm that can be treated conservatively

6. Device Description

The Disposable Hemostatic Closure Clip Device is a sterile, single-use endoscopic clipping device, intended for flexible endoscopy and for compression of tissue in the gastrointestinal (GI) tract, for hemostasis or for treating gastrointestinal organ wall lesions, and for making of lesions. The device is indicated for clip placement within the GI tract for the purpose of:

a. endoscopic marking

b. hemostasis for:

- mucosal/submucosal defects < 3cm
- bleeding ulcers
- arteries < 2 mm
- polyps < 1.5 cm in diameter
- diverticuli in the colon

c. Closure of GI tract luminal perforations < 20mm that can be treated conservatively.

The Disposable Hemostatic Closure Clip Device consists of one pre-loaded clip and delivery device for single patient use only. The clip is made of nickel-titanium alloy with good superelasticity performance. The clip is pre-loaded in the barrel at the end of the delivery system through its deformation.

The proposed device has twenty-four (24) specifications that vary to the outer diameter of

the clip: φ14.5 mm, φ17.0 mm; working length: 1650 mm, 1950 mm, 2350 mm, 2700 mm; and whether the outer tube is coated or not.

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 Hemostatic Closure Clip Device incorporates substantially equivalent device materials, design, configuration, packaging fundamental technology, sterilization process and intended use as those featured in the Predicate Device OTSC™ (Over-The-Scope-Clip) System Set (K101428).

Comparison to Predicate Devices:

ITEM	**Proposed Device** Disposable Hemostatic Closure Clip Device	**Predicate Device (K101428)** OTSC™ (Over-The-Scope-Clip) System Set	**Remark**
Product Code	PKL	PKL	Same
Regulation No.	876.4400 Hemorrhoidal ligator	876.4400 Hemorrhoidal ligator	Same
Class	II	II	Same
Intended use	The device for flexible endoscopy and for compression of tissue in the gastrointestinal (GI) tract, for hemostasis or for treating gastrointestinal organ wall lesions, and for making of lesions. The Device is indicated for clip placement within the GI tract for the purpose of: a .Endoscopic Marking b. Hemostasis for: - Mucosal/Submucosal defects < 3cm - Bleeding Ulcers - Arteries < 2 mm - Polyps < 1.5 cm in diameter - Diverticula in the Colon c. Closure of GI tract luminal	The OTSC system set is indicated for use in flexible endoscopy and for the compression of tissue in the gastrointestinal tract, for haemostasis or for treating lesions of the wall of gastrointestinal organs. Marking of lesions. The OTSC clip is indicated for clip placement within the gastrointestinal (GI) tract for the purpose of: - Endoscopic marking – Hemostasis for: - Mucosal/submucosal defects < 3 cm - Bleeding ulcers - Arteries < 2 mm - Polyps < 1.5 cm in diameter	Same

ITEM	**Proposed Device** Disposable Hemostatic Closure Clip Device	**Predicate Device (K101428)** OTSC™ (Over-The-Scope-Clip) System Set	**Remark**
	perforations < 20mm that can be treated conservatively	- Diverticula in the colon - Closure of GI tract luminal perforations < 20 mm that can be treated conservatively	
Single Use	Yes	Yes	Same
Supplied in Sterile	Yes	Yes	Same
Configuration	Clip, delivery system	Clip, Delivery System	Same
Clip (Material)	Niti	Niti	Same
Clip Width (mm)	φ14.5, φ17	9, 10, 11	The clip of proposed device is circular in shape, while the clip of predicate device is rectangular in shape
Scope Compatibility (mm)	φ 9.5---φ14	φ 9.5---φ14	Same
Working Length (mm)	1650, 1950, 2350, 2700	1650, 2200	Similar
Principles of Operation	Use negative pressure to attract tissue, operate handle and release clip	Use negative pressure to attract tissue, operate handle and release clip	Same
Biocompatibility	Comply with ISO10993-1	Comply with ISO10993-1	Same
Packaging	Single-use EO sterilized pouch with one device per pouch	Single-use EO sterilized pouch with one device per pouch	Same
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	Same
Sterilization	EO Sterilized, SAL: 10^{-6}	EO Sterilized, SAL: 10^{-6}	Same
Shelf Life	3 years	3 years	Same

ITEM	**Proposed Device** Disposable Hemostatic Closure Clip Device	**Predicate Device (K101428)** OTSC™ (Over-The-Scope-Clip) System Set	**Remark**
Labeling	Conforms to 21 CFR part 801	Conforms to 21 CFR part 801	Same

The proposed device is similar in design to Predicate Device OTSC™ (Over-The-Scope-Clip) System Set (K101428), the dimensions of proposed device are different to the predicate device. All comparative non-clinical performance testings have been tested and have met the requirements of substantial equivalence to the predicate device.

Therefore, the difference between proposed device and predicated device is considered not to affect the substantially equivalency between the proposed and predicate devices concerning the safety and effectiveness.

8. Performance Data

The biocompatibility evaluation for the Disposable Hemostatic Closure Clip Device was conducted in accordance with FDA Guidance, Use of International Standard ISO-10993-1, 'Biological Evaluation of Medical Devices Part 1: Evaluation and Testing within a risk management process" issued on September 4, 2020. The following tests were conducted for the clip of Disposable Hemostatic Closure Clip Device:

1) Cytotoxicity Study
2) ISO Guinea Pig Maximization Sensitization Test
3) ISO Intracutaneous Study in Rabbits
4) Acute Systemic Toxicity
5) Material Mediated Pyrogenicity in Rabbits
6) Hemolysis
7) ISO Muscle Implantation Study, 1 Weeks
8) ISO Muscle Implantation Study, 4 Weeks
9) ISO Muscle Implantation Study, 13 Weeks

The following tests were conducted for the delivery system of Disposable Hemostatic Closure Clip Device:

1) Cytotoxicity Study
2) ISO Guinea Pig Maximization Sensitization Test
3) ISO Intracutaneous Study in Rabbits
4) ISO Acute Systemic Toxicity Study
5) USP Rabbit Pyrogen Study

Sterilization validation of Disposable Hemostatic Closure Clip Device was carried out in

accordance with ISO 11135 Second edition 2014-07-15 Sterilization of health-care products - Ethylene oxide - Requirements for the development, validation and routine control of a sterilization process for medical devices [Including: Amendment 1 (2018)]

Shelf-life testing and packaging integrity testing of Disposable Hemostatic Closure Clip Device 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 and ISO 11607-1:2019: Packaging for terminally sterilized medical devices - Part 1: Requirements for materials, sterile barrier systems and packaging systems and ISO 11607-2:2019: Packaging for terminally sterilized medical devices - Part 2: Validation requirements for forming, sealing and assembly processes. Three-year accelerated aging test have been performed to demonstrate the stability during the shelf life.

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.

During design verification, the following bench tests were performed on Disposable Hemostatic Closure Clip Device:

- Dimension
- Release Performance
- Clip Recovery Performance
- Closure Force of Clip
- Connection Force between Cable and Handle
- Connection Force between Barrel and Soft Boot
- Endoscope Adaptability
- Deployment and Clip Persistence

The results of all the performance testings demonstrated that the proposed device met the predetermined acceptance criteria and is substantial equivalence to the predicate device.

9. Animal Test Conclusion

No animal study is included in this submission.

10. Clinical Test Conclusion

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 Hemostatic Closure Clip Device** has been shown to be appropriate for its intended use and is considered to be substantially equivalent to the currently cleared predicate device **OTSC™ (Over-The-Scope-Clip) System Set (K101428).**