June 1, 2018

Micro-Tech (Nanjing) CO., Ltd.
Becky Li
Quality and Regulatory Affairs Director
NO. 10 Gaoke Third Road
Nanjing, Jiangsu 210032
China

Re: K180325
Trade/Device Name: Single Use MultiClip Device
Regulation Number: 21 CFR§ 876.4400
Regulation Name: Hemorrhoidal Ligator
Regulatory Class: II
Product Code: PKL
Dated: April 19, 2018
Received: April 23, 2018

Dear Becky Li:

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Joyce M. Whang -S

for

Benjamin R. Fisher, Ph.D.
Director
Division of Reproductive, Gastro-Renal,
and Urological Devices
Office of Device Evaluation
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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*

K180325

Device Name
Single Use MultiClip Device

Indications for Use *(Describe)*

The Single Use MultiClip Device is indicated for endoscopic clip placement within the gastrointestinal tract 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,
(3) as a supplementary method, 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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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Tab 7

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: **_K180325_____**

1. **Date of Preparation: 2018-05-30**

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: Becky Li

Position: Quality and Regulatory Affairs Director

Tel: +86-25-58646378

Fax: +86-25-58350006

Email: ln@micro-tech.com.cn

3. **Identification of Proposed Device**

Trade Name: Single Use MultiClip Device

Common Name: Hemostasis Clipping Device

Regulatory Information

Classification Name: Hemorrhoidal ligator

Classification: 2

Product Code: PKL

Regulation Number: 876.4400

Review Panel: Gastroenterology/Urology

Intended Use Statement:

This device is intended to be used for endoscopic marking, hemostasis for mucosal/submucosal defects in digestive tract.

4. Identification of Predicate Device

510(k) Number: K152001

Product Name: Sterile Repositionable Hemostasis Clipping Device

5. Indications for Use

The Single Use MultiClip Device is indicated for endoscopic clip placement within the gastrointestinal tract 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,

(3) as a supplementary method, closure of GI tract luminal perforations <20mm that can be treated conservatively

6. Device Description

The proposed device **Single Use MultiClip Device** is a sterile, single-use endoscopic clipping device, intended to be used for endoscopic marking, hemostasis for mucosal/submucosal defects in digestive tract.

It consists of two main components, delivery system and clip assembly. And it has 3 or 5 clips, the 3 or 5 clips could be continuous released by the delivery system.

7. Comparison of Technological Characteristics

The **Single Use MultiClip Device** incorporates substantially equivalent device

materials, design, configuration, packaging fundamental technology, manufacturing processes, sterilization process and intended use as those featured in the Micro-Tech (Nanjing) CO., Ltd. predicate devices.

Comparison to predicate Devices:

Item	Proposed Device **Single Use MultiClip Device**	Comparison to Predicate Devices
Product Code	PKL	Same
Regulation No.	876.4400	Same
Class	2	Same
Supplied Sterile	Yes	Same
Configuration	Delivery system and clip assembly	Same
Open width	10mm	Similar
Smallest working channel	2.8mm	Same
Working Length	1250mm, 1650mm, 1950mm, 2350mm	Similar
Indications for Use	The **Single Use MultiClip Device** is indicated for endoscopic clip placement within the gastrointestinal tract 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, (3) as a supplementary method, closure of GI tract luminal perforations <20mm that can be treated conservatively	Same
Single Use	Yes	Same
Packaging	Single-use EO sterilized rigid tray with a sealable cover	Similar
Shelf Life	Two years	Similar

8. Performance Data

The proposed device the **Single Use MultiClip Device** meets the requirements of AAMI ANSI ISO 10993-1 :2009/(R)2013 “Biological Evaluation of Medical Devices – Part 1: Evaluation and Testing Within A Risk Management Process”, 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”, and ISO 10993-7 Second Edition 2008-10-15 “Biological evaluation of medical devices - Part 7: ethylene oxide sterilization residuals”,

ASTM F88/F88M-15, Standard Test Method For Seal Strength Of Flexible Barrier Materials,

ASTM F1929 - 15, Standard Test Method For Detecting Seal Leaks In Porous Medical Packaging By Dye Penetration,

AAMI ANSI ST72:2011/(R)2016 bacterial endotoxins - test methods, routine monitoring, and alternatives to batch testing,

ASTM F1886/F1886M – 09 Standard Test Method for Determining Integrity of Seals for Flexible Packaging by Visual Inspection,

ASTM F1980 - 16，Standard Guide for Accelerated Aging of Sterile Barrier Systems for Medical Devices,

ISO 11737-1 Second edition 2006-04-01, sterilization of medical devices - microbiological methods - part 1: determination of a population of microorganisms on products [including: technical corrigendum 1 (2007)] ,

USP 40-NF35:2017, <71> Sterility tests,

ASTM F2052-15 Standard Test Method for Measurement of Magnetically Induced Displacement Force on medical devices in the magnetic resonance environment. (Materials) ,

ASTM F2119-07 Standard Test Method for Evaluation of MR Image Artifacts from Passive Implants , and

ASTM F2182 – 11a Standard Test Method for Measurement of Radio Frequency

Induced Heating On or Near Passive Implants During Magnetic Resonance Imaging.

The following bench tests were performed on the **Single Use MultiClip Device**

Dimensional verification	Mechanical Integrity of Clip Assembly
Clamping Strength Testing	Tensile Strength Testing
Release Force Testing	Rotation Testing
Multiple Clip Deployment Testing	Reposition Testing

The proposed device has 3 or 5 clips, the 3 or 5 clips could be continuous released by the delivery system, the model with 5 clips as the worst case to do the bench tests, each clip in the 5 clips has done the related bench tests, and conduct the substantially equivalent analysis to the predicate device

The testing performed demonstrated that the proposed device and predicate device are substantially equivalent.

9. Clinical Test Conclusion

No clinical study is included in this submission.

10. Substantially Equivalent (SE) Conclusion

Based on the indications for use, technological characteristics, and safety and performance testing, the **Single Use MultiClip Device** has been shown to be appropriate for its intended use and is considered to be substantially equivalent to the currently cleared the **Sterile Repositionable Hemostasis Clipping Device (K152001).**