



Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

January 6, 2017

Micro-Tech (Nanjing) Co., Ltd.
Becky Li
Quality Director
No. 10 Gaoke Third Road
Nanjing, Jiangsu 210032
China

Re: K161463
Trade/Device Name: SureClip(TM) Repositionable Hemostasis Clip
Regulation Number: 21 CFR§ 876.4400
Regulation Name: Hemorrhoidal Ligator
Regulatory Class: II
Product Code: PKL
Dated: November 21, 2016
Received: November 28, 2016

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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>. 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.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,


Benjamin R. Fisher -S

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

Indications for Use

510(k) Number (if known)
K161463

Device Name
SureClip(TM) Repositionable Hemostasis Clip

Indications for Use (Describe)

The SureClip(TM) Repositionable Hemostasis Clip 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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRASStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."



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: **K161463**

1. Date of Preparation: 2017-01-05

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 Director

Tel: +86-25-58646378

Fax: +86-25-58744269

Email: ln@micro-tech.com.cn

3. Identification of Proposed Device

Trade Name: SureClipTM Repositionable Hemostasis Clip

Common Name: Hemostasis Clipping 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

**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 SureClip™ Repositionable Hemostasis Clip 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 **SureClip™ Repositionable Hemostasis Clip** 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 is offered in different dimensions.

7. Comparison of Technological Characteristics



The **SureClip™ Repositionable Hemostasis Clip** 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 SureClip™ Repositionable Hemostasis Clip	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	8mm, 11mm and 16mm	Similar
Minimal working channel	2.8mm	Same
Working Length	1650mm, 1950mm and 2350mm	Same
Indications for Use	The SureClip™ Repositionable Hemostasis Clip 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 pouch with one device per pouch	Same
Shelf Life	Three years	Same



8. Performance Data

The proposed device the **SureClip™ Repositionable Hemostasis Clip** meets the requirements of ISO 10993-1 “Biological Evaluation of Medical Devices – Part 1: Evaluation and Testing Within A Risk Management Process”, ISO 11135 “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 “Biological evaluation of medical devices - Part 7: ethylene oxide sterilization residuals”,

The following bench tests were performed on the **SureClip™ Repositionable Hemostasis Clip**,

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

The testing performed demonstrated that the proposed and predicate delivery systems are substantial 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 **SureClip™ Repositionable Hemostasis Clip** 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)**.