October 3, 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: K222354
Trade/Device Name: Elastic Traction System
Regulation Number: 21 CFR 876.4410
Regulation Name: Endoscopic traction device
Regulatory Class: Class II
Product Code: QSW
Dated: July 29, 2022
Received: August 4, 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)*

K222354

Device Name

Elastic Traction System

Indications for Use *(Describe)*

The Elastic Traction System is indicated for adult only for use in flexible Endoscopy to provide retraction to assist in tissue resection, exposure, and removal of tissue within the stomach and colon.

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: **K222354**

1. Date of Preparation: 2022-09-30

2. Sponsor Identification

Micro-Tech (Nanjing) Co., Ltd.

No.10 Gaoke Third Road, Nanjing National Hi-Tech, Industrial Development Zone, Nanjing, Jiangsu Province, PRC

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3. Identification of Proposed Device

Trade Name: Elastic Traction System

Common Name: Endoscopic Traction Device

Regulatory Information

Device Classification Name: Endoscopic Traction Device

Classification: 2

Product Code: QSW

Regulation Number: 21 CFR 876.4410

Review Panel: Gastroenterology/Urology

4. Identification of Predicate Device

De Novo Number: DEN220006

Product Name: ProdiGI Traction Wire

Manufacturer: Covidien LLC.

5. Indications for Use

The Elastic Traction System is indicated for adult only for use in flexible Endoscopy to provide retraction to assist in tissue resection, exposure, and removal of tissue within the stomach and colon.

6. Device Description

The proposed device, Elastic Traction System, consists of 2 components, an Elastic Traction Device, and a clipping device (Fig. 1). Two components are single use device.

The Elastic Traction Device is a single use tissue traction device. It is consisting of clip assembly, silicone band and delivery system. The silicone band is consisting of three rings. Ring A is preloaded with the clip.

The Clipping Device is a single use device, and its purpose is to use it as a second clip. The second clip is used to engage the silicone band of the previously anchored clip of Elastic Traction Device.

7. Comparison of Technological Characteristics

The **Elastic Traction System** substantially equivalent device materials, design, configuration, packaging, sterilization process and intended use as those featured in the predicate device **ProdiGI Traction Wire (DEN220006).**

Comparison to predicate Devices:

Characteristics	Proposed Device Elastic Traction System	Predicated Device ProdiGI Traction Wire (DEN220006)	Remark
Product Code	QSW	QSW	Same
Class	II	II	Same
Regulation	Endoscopic Traction Device	Endoscopic Traction Device	Same

Characteristics	Proposed Device Elastic Traction System	Predicated Device ProdiGI Traction Wire (DEN220006)	Remark
Description			
Regulation number	876.4410	876.4410	Same
Indications for Use	The Elastic Traction System is indicated for adult only for use in flexible Endoscopy to provide retraction to assist in tissue resection, exposure, and removal of tissue within the stomach and colon.	The Medtronic ProdiGI Traction Wire is indicated to grasp tissue within the esophagus, stomach, and colon of adults during an Endoscopic Submucosal Dissection (ESD) procedure.	Similar
Target population	Adults	Adults	Same
Use Condition	Endoscopy suite, used with a compatible Endoscope	Endoscopy suite, used with a compatible Endoscope	Same
Mechanics of Action	Manual	Manual	Same
Operation Principle	Anchor the edge of tissue on the silicone band with endoscopic clips and retract the tissue through own elastic force of the silicone band.	Anchor the edge of tissue on the wire with endoscopic clips and retract the tissue through restoring force of the wire .	Similar
General Configuration	2 Clips Silicone band	2 Clips Metal Wire band	Similar
Compatible endoscopy working channel	2.8 mm or larger	2.8 mm or larger	Same
Working length	1650 mm, 2350 mm	2300 mm	Similar
Silicone band/Traction wire length	The longest distance of the rings center is 7.1 mm	20 mm, 35mm	Similar
Main Patient-contact Material	Silicone rubber	Metal	Different
Single Use	Yes	Yes	Same
Supplied in Sterile	Yes	Yes	Same

Characteristics	Proposed Device Elastic Traction System	Predicated Device ProdiGI Traction Wire (DEN220006)	Remark
Rx-only	Yes	Yes	Same
Non-clinical Performance	Performs as intended under anticipated conditions of use	Performs as intended under anticipated conditions of use	SE
Usability	The intended user can safely and correctly use the proposed device.	The intended user can safely and correctly use the proposed device.	SE
In vivo study	Animal study performs as intended under anticipated conditions of use	In vivo performance testing performs as intended under anticipated conditions of use	SE
Biocompatibility	Comply with ISO 10993-1	Comply with ISO 10993-1	SE
Shelf Life	Comply with ASTM F1980	Comply with ASTM F1980	SE
Labeling	Conforms to 21 CFR part 801	Conforms to 21 CFR part 801	SE

The proposed device and the predicate device both used the two clips to anchor the edge of the tissue and lift the mucosal to provide the visualization with a connecting band during the ESD procedure. The main difference between the two devices is the material of the connecting band, the proposed device used the silicon rubber which provides retraction with elastic force of deforming, while the predicate device used the metal wire with restoring force of memory function.

8. Performance Data

Performance testing was conducted to demonstrate the essential performance of the proposed device **Elastic Traction System** and confirmed that the proposed device works as intended.

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

- Dimension
- Release Force
- Clamping Strength
- Tensile strength
- Elastic Performance
- Rotation Performance
- Repeated Opening and Closing Performance

- Clip Opening and Closing Forces
- Endoscope Compatibility
- Endoscope Damage

Usability assessment was performed to demonstrate that the intended user can safely and correctly use 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. Two-years aging test was 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+A1:2019 “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".

The results of performance testing demonstrate that the proposed device **Elastic Traction System** is considered safe and effective for its intended use.

9. Animal Study

The proposed device **Elastic Traction System** has conducted animal test according to 21 CFR §58 (GLP Regulations) to demonstrate the safety and effectiveness.

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 **Elastic Traction System** has been shown to be appropriate for its intended use and is considered to be substantially equivalent to the currently cleared predicate device the **ProdiGI** approved under **DEN220006.**