May 29, 2019

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

Re: K182910
Trade/Device Name: Segmented Esophageal Stent System
Regulation Number: 21 CFR§ 878.3610
Regulation Name: Esophageal Prosthesis
Regulatory Class: II
Product Code: ESW
Dated: April 29, 2019
Received: May 2, 2019

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. 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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

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,

For
Shani P. Haugen, Ph.D.
Acting, Assistant Division 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K182910

Device Name
Segmented Esophageal Stent System

Indications for Use *(Describe)*
The Segmented Esophageal Stent System is intended for maintaining esophageal luminal patency in esophageal strictures caused by intrinsic, or extrinsic malignant tumors only, and occlusion of concurrent esophageal fistula.

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
PRAStaff@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."

Tab 2

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: **K182910**

1. Date of Preparation:

2019-05-22

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 & Regulatory Affairs Director

Tel: +86-25-58646378

Fax: +86-25-58350006

Email: Beckyli_mt@outlook.com

3. Identification of Proposed Device

Trade Name: Segmented Esophageal Stent System

Common Name: Prosthesis, Esophageal

Regulatory Information

Classification Name: Esophageal Prosthesis

Classification: 2

Product Code: ESW

Regulation Number: 878.3610

Review Panel: Gastroenterology/Urology

4. Identification of Predicate Device

510(k) Number: K072094

Product Name: CHOOSTENT™ Covered Esophageal Stent

Manufacturer: M. I. Tech Co., Ltd.

5. Indications for Use

The Segmented Esophageal Stent System is intended for maintaining esophageal luminal patency in esophageal strictures caused by intrinsic, or extrinsic malignant tumors only, and occlusion of concurrent esophageal fistula.

6. Device Description

The stent is provided pre-loaded in the delivery system. The stent is made up of several segments. The main frame is woven by Nitinol wire, and the connecting part is PTFE connecting loop. The stent with this segmented structure can flexibly conform to the curvature of the human body lumen, thereby reducing the stimulation of the end to the lumen. Silicone membrane applied to the stent covers the complete body of the stent along both flanges, which means the segmented esophageal stent is a fully covered stent. The stent is formed with a flange at either end. The increased diameter of the stent at the stent ends helps provide resistance to migration. The covering is intended to reduce the risk of tissue ingrowth and provides a occlusion for esophageal fistulas. To aid in visibility under fluoroscopy there are 4 bands at either end of the stent and 2 bands at the middle of the stent. The stent has a retrieval loop which can be used to reposition the stent during the initial placement procedure if desired. The delivery system allows for desheathing to deploy the stent and recapturing the stent during stent deployment. The device is supplied sterile, intended for single use only and is available for prescription use only. Use of this device is restricted to a trained healthcare professional.

7. Comparison of Technological Characteristics with a Predicate Device

The **Segmented Esophageal Stent System** incorporates substantially equivalent device materials, design, configuration, packaging fundamental technology, manufacturing processes, sterilization process and features the same intended use with the predicate device, namely the Esophageal Stent System manufactured by M. I. Tech Co., Ltd., under K072094.

The proposal device is substantially equivalent to the currently marketed devices, CHOOSTENT™ covered esophageal stent, K072094.

The following table is the technological comparison between the proposed device and predicate device CHOOSTENT™ covered esophageal stent (K072094).

Table 2 Technological comparison between the proposed device and predicate device

ITEM	Proposed Device Segmented Esophageal Stent System	Predicate Device (K072094) CHOOSTENT™ covered esophageal stent	Remark
Product Code	ESW	ESW	Same
Regulation No.	878.3610	878.3610	Same
Class	2	2	Same
Configuration	Stent and delivery system	Stent and delivery system	Same
Indications for Use	Segmented Esophageal Stent System is intended for maintaining esophageal luminal patency in esophageal strictures caused by intrinsic, or extrinsic malignant tumors only, and occlusion of concurrent esophageal fistula.	The CHOOSTENT™ covered esophageal stent is intended for maintaining esophageal luminal patency in esophageal strictures caused by intrinsic and or extrinsic malignant tumors only and occlusion of concurrent esophageal fistula.	Same
Single Use	Yes	Yes	Same
Diameter of Stent (mm)	18,20,22	18	Different
Length of Stent (mm)	60, 80, 100, 120, 140	80, 110, 140, 170	Different
Maximum OD (D) of Delivery System (mm)	6.7	6.0	Different
Working Length (mm)	650	700	Different

ITEM	Proposed Device Segmented Esophageal Stent System	Predicate Device (K072094) CHOOSTENT™ covered esophageal stent	Remark
Covering	Fully Covered	Fully Covered	Same
Shelf life	2 years	3 years	Different
Packaging	EO sterilized pouch with one device per pouch	EO sterilized pouch with one device per pouch	Same
Biocompatibility	Conform to ISO 10993-1	Conform to ISO 10993-1	Same
Sterilization	EO Sterilized, SAL:10^{-6}	EO Sterilized, SAL:10^{-6}	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
Labeling	Conform to 21 CFR part 801	Conform to 21 CFR part 801	Same

8. Performance Data

The Segmented Esophageal Stent System was conducted in accordance with, ISO 10993-1: 2009 “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 FDA’s biocompatibility guidance, Use of International Standard ISO-10993-7, “Biological Evaluation of Medical Devices7: Ethylene Oxide Sterilization Residuals’, the following tests were conducted:

Stent Biocompatibility Testing:

- Vitro Cytotoxicity
- Skin Sensitization
- Irritation
- Acute Systemic Toxicity

- Pyrogen
- Salmonella Reverse Mutation Test
- In Vitro Mammalian Cell Gene Mutation Test
- Muscle Implant

Delivery System Biocompatibility Testing:

- Vitro Cytotoxicity
- Skin Sensitization
- Irritation
- Acute Systemic Toxicity

The device specific guidance document was consulted in preparing this premarket submission, *VIII Performance testing-Bench of Guidance for the Content of Premarket Notifications for Esophageal and Tracheal Prostheses* issued April 28th, 1998, the following tests were conducted for the subject device:

- ✧ Visual Inspection
- ✧ Dimension Testing
- ✧ Deployment Force Testing
- ✧ Expansion Force Testing
- ✧ Compression Force Testing
- ✧ Corrosion Testing
- ✧ Tensile Strength Testing
- ✧ Sterility Testing
- ✧ Shelf Life Testing
- ✧ MR Compatibility Testing

The testing performed demonstrated that the proposed device and predicate device are 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 **Segmented Esophageal Stent System** has been shown to be appropriate for its intended use and is considered to be substantially equivalent to the currently cleared the CHOOSTENT™ Covered Esophageal Stent (K072094).