June 21, 2018

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

Re: K172813
Trade/Device Name: Esophageal Stent System
Regulation Number: 21 CFR§ 878.3610
Regulation Name: Esophageal Prosthesis
Regulatory Class: II
Product Code: ESW
Dated: April 13, 2018
Received: April 17, 2018

Dear Becky Li:

This letter corrects our substantially equivalent letter of May 18, 2018.

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 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
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)*
K172813

Device Name
Esophageal Stent System

Indications for Use *(Describe)*
The Esophageal Stent System is intended for maintaining esophageal luminal patency in esophageal strictures caused by intrinsic and/or extrinsic malignant tumors, 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:

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*"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: **K172813**

1. **Date of Preparation: 05/22/2018**

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 & RA Director

**Tel:** +86-25-58646378

**Fax:** +86-25-58350006

**Email:** ln@micro-tech.com.cn

3. **Identification of Proposed Device**

**Trade Name:** 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: K091510

Product Name: WallFlex Esophageal Fully Covered Stent System

## 5. Indications for Use

Esophageal Stent System 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.

## 6. Device Description

The Esophageal Stent System consists of a self-expanding metal stent and a stent introduction system. The stent is provided pre-loaded in the introduction system. The handle allows for desheathing to deploy the stent and resheathing recapturing the stent during stent deployment. The stent is woven from nitinol wire. 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. A silicone membrane applied to the stent covers the complete body of the stent along with **part or fully** of both flanges. The covering is intended to reduce the risk of tissue ingrowth and provides a seal for esophageal fistulas. To aid in visibility under fluoroscopy there are four bands at either end of the stent. The stent has a lasso loop which can be used to reposition the stent during the initial placement procedure if desired. 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.

The detail dimension information of the proposed device is as follows:

Table 1 Dimension information of proposed device (Unit: mm)

| No | Model | Diameter of Stent (D) | Diameter of Stent (D1,D2) | Length of Stent (L) | Length of Stent (L0) | Maximum OD (D) of Delivery System | Working Length (L) | Covering |
|---|---|---|---|---|---|---|---|---|
| 1 | NST01-222-18.060 | 18 | 23 | 060 | 030 | 6.7 | 650 | Partially Covered |
| 2 | NST01-222-18.080 | 18 | 23 | 080 | 050 | 6.7 | 650 | Partially Covered |
| 3 | NST01-222-18.100 | 18 | 23 | 100 | 070 | 6.7 | 650 | Partially Covered |
| 4 | NST01-222-18.120 | 18 | 23 | 120 | 090 | 6.7 | 650 | Partially Covered |
| 5 | NST01-222-18.140 | 18 | 23 | 140 | 110 | 6.7 | 650 | Partially Covered |
| 6 | NST01-222-18.150 | 18 | 23 | 150 | 120 | 6.7 | 650 | Partially Covered |
| 7 | NST01-222-20.060 | 20 | 25 | 060 | 030 | 6.7 | 650 | Partially Covered |
| 8 | NST01-222-20.080 | 20 | 25 | 080 | 050 | 6.7 | 650 | Partially Covered |
| 9 | NST01-222-20.100 | 20 | 25 | 100 | 070 | 6.7 | 650 | Partially Covered |
| 10 | NST01-222-20.120 | 20 | 25 | 120 | 090 | 6.7 | 650 | Partially Covered |
| 11 | NST01-222-20.140 | 20 | 25 | 140 | 110 | 6.7 | 650 | Partially Covered |
| 12 | NST01-222-20.150 | 20 | 25 | 150 | 120 | 6.7 | 650 | Partially Covered |
| 13 | NST01-222-22.060 | 22 | 27 | 060 | 030 | 6.7 | 650 | Partially Covered |
| 14 | NST01-222-22.080 | 22 | 27 | 080 | 050 | 6.7 | 650 | Partially Covered |
| 15 | NST01-222-22.100 | 22 | 27 | 100 | 070 | 6.7 | 650 | Partially Covered |
| 16 | NST01-222-22.120 | 22 | 27 | 120 | 090 | 6.7 | 650 | Partially Covered |
| 17 | NST01-222-22.140 | 22 | 27 | 140 | 110 | 6.7 | 650 | Partially Covered |
| 18 | NST01-222-22.150 | 22 | 27 | 150 | 120 | 6.7 | 650 | Partially Covered |

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510K Summary

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|---|---|---|---|---|---|---|---|---|
| 19 | NST01-224-18.060 | 18 | 23 | 060 | 030 | 6.7 | 650 | Fully Covered |
| 20 | NST01-224-18.080 | 18 | 23 | 080 | 050 | 6.7 | 650 | Fully Covered |
| 21 | NST01-224-18.100 | 18 | 23 | 100 | 070 | 6.7 | 650 | Fully Covered |
| 22 | NST01-224-18.120 | 18 | 23 | 120 | 090 | 6.7 | 650 | Fully Covered |
| 23 | NST01-224-18.140 | 18 | 23 | 140 | 110 | 6.7 | 650 | Fully Covered |
| 24 | NST01-224-18.150 | 18 | 23 | 150 | 120 | 6.7 | 650 | Fully Covered |
| 25 | NST01-224-20.060 | 20 | 25 | 060 | 030 | 6.7 | 650 | Fully Covered |
| 26 | NST01-224-20.080 | 20 | 25 | 080 | 050 | 6.7 | 650 | Fully Covered |
| 27 | NST01-224-20.100 | 20 | 25 | 100 | 070 | 6.7 | 650 | Fully Covered |
| 28 | NST01-224-20.120 | 20 | 25 | 120 | 090 | 6.7 | 650 | Fully Covered |
| 29 | NST01-224-20.140 | 20 | 25 | 140 | 110 | 6.7 | 650 | Fully Covered |
| 30 | NST01-224-20.150 | 20 | 25 | 150 | 120 | 6.7 | 650 | Fully Covered |
| 31 | NST01-224-22.060 | 22 | 27 | 060 | 030 | 6.7 | 650 | Fully Covered |
| 32 | NST01-224-22.080 | 22 | 27 | 080 | 050 | 6.7 | 650 | Fully Covered |
| 33 | NST01-224-22.100 | 22 | 27 | 100 | 070 | 6.7 | 650 | Fully Covered |
| 34 | NST01-224-22.120 | 22 | 27 | 120 | 090 | 6.7 | 650 | Fully Covered |
| 35 | NST01-224-22.140 | 22 | 27 | 140 | 110 | 6.7 | 650 | Fully Covered |
| 36 | NST01-224-22.150 | 22 | 27 | 150 | 120 | 6.7 | 650 | Fully covered |

## 7. Comparison of Technological Characteristics with a Predicate Device

The **Esophageal Stent System** incorporates substantially equivalent device materials, design, configuration, packaging fundamental technology, manufacturing processes, sterilization process and intended use as those featured in the Boston Scientific Corporation Predicate Device, WallFlex Esophageal Fully Covered Stent System, under K091510.

The proposal device is substantially equivalent to the currently marketed devices, WallFlex Esophageal Fully Covered Stent System, K091510 cleared June 26, 2009.

The following table is the technological comparison between the proposed device and predicate device WallFlex Esophageal Fully Covered Stent System (K091510).

Table 2 Technological comparison between the proposed device and predicate device

| ITEM | Proposed Device Esophageal Stent System | Predicate Device (K091510) WallFlex Esophageal Fully Covered Stent System | Remark |
|---|---|---|---|
| Diameter of Stent (mm) | 18,20,22 | 18,23 | One more different diameter than predicate device. More diameter could provide more choices. |
| Length of Stent (mm) | 60, 80, 100, 120, 140, 150 | 103, 123, 153<br>105, 125, 155 | More short lengths than predicate device. More length can provide more choices for users |
| Maximum OD (D) of Delivery System (mm) | 6.7 | 6.17 | Different but similar |
| Working Length (mm) | 650 | 780 | Different working length, but similar |

| | | | |
|---|---|---|---|
| Covering | Partially Covered, Fully Covered | Fully Covered | The proposed device includes partially covered and fully covered. The predicate device only has fully covered. |
| Main Stent material | Nitinol, Silicone | Nitinol, Silicone | Same |
| Main Introduction system materials | PTFE, Pebax | PTFE, Pebax | Same |
| Indications for Use | Esophageal Stent System 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. | The WallFlex Esophageal Fully Covered Stent System is intended for maintaining esophageal luminal patency in esophageal strictures caused by instrinsic and/or extrinsic malignant tumors, and occlusion of concurrent esophageal fistula. | Same |
| Stent function | maintaining esophageal luminal patency in esophageal strictures | maintaining esophageal luminal patency in esophageal strictures | Same |
| Shelf life | 2 years | 1.5 years | Different, longer shelf life than predicate device |
| Principle of operation | The proposed device consists of the stent and delivery system. The outer tube of the delivery system serves to constrain the stent before deployment and reposition the stent, if desired, after partial deployment. Loosen the safe lock, then withdraw the front handle to deploy the stent. Take the opposite action to reposition the stent | The proposed device consists of the stent and delivery system. The outer tube of the delivery system serves to constrain the stent before deployment and reposition the stent, if desired, after partial deployment. Loosen the safe lock, then withdraw the front handle to deploy the stent. Take the opposite action to reposition the stent | Same |
| Single Use | Yes | Yes | 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 | MR conditional scanning parameters are different |

## 8. Performance Data

The biocompatibility evaluation for the 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” and FDA’s biocompatibility guidance, Use of International Standard ISO-10993-1, “Biological Evaluation of Medical Devices Part 1: Evaluation and Testing within a risk management process” (June 16, 2016), the following tests were conducted:

***Biocompatibility Testing on Stent:***

- Cytotoxicity
- Sensitization
- Intracutaneous Reactivity
- Acute Systemic Toxicity
- Material-mediated Pyrogenicity
- Salmonella Reverse Mutation
- Implantation
- Toxicological Risk Assessment based on Chemical Characterization

***Biocompatibility Testing on Introduction System:***

- Cytotoxicity
- Sensitization
- Irritation

The device specific guidance document was consulted in preparing this premarket submission, 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

## 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 **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 WallFlex Esophageal Fully Covered Stent System(K091510).