Micro-Tech (Nanjing) Co., Ltd.
Sally He
RA Engineer
No.10 Gaoke Third Road, Nanjing National Hi-Tech
Industrial Development Zone
Nanjing, Jiangsu Province 210032
China

Re: K220424
Trade/Device Name: Through the Scope Tracheal Stent System
Regulation Number: 21 CFR 878.3720
Regulation Name: Tracheal Prosthesis
Regulatory Class: Class II
Product Code: JCT
Dated: June 9, 2022
Received: June 13, 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,

Brandon Blakely, Ph.D.
Assistant Director
DHT1C: Division of Sleep Disordered
Breathing, Respiratory, and
Anesthesia Devices
OHT1: Office of Ophthalmic, Anesthesia,
Respiratory, ENT and Dental 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)*
K220424

Device Name
Through the Scope Tracheal Stent System

Indications for Use *(Describe)*
The Through the Scope Tracheal Stent System is indicated for use in the treatment of tracheobronchial strictures caused by malignant neoplasms.

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: **K220424**

1. **Date of Preparation: 2022-07-07**

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: Sally He

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3. **Identification of Proposed Device**

Trade Name: Through the Scope Tracheal Stent System

Common Name: Tracheal Stent

Regulatory Information

Classification Name: Tracheal Prosthesis

Classification: 2

Product Code: JCT

Regulation Number: 878.3720

Review Panel: Anesthesiology

4. Identification of Predicate Device

510(k) Number: K202204

Product Name: Tracheal Stent System (OTW)

Manufacturer: Micro-Tech (Nanjing) Co., Ltd.

5. Indications for Use

The Through the Scope Tracheal Stent System is indicated for use in the treatment of tracheobronchial strictures caused by malignant neoplasms.

6. Device Description

The Through the Scope Tracheal Stent System consists of a flexible delivery system preloaded with a self-expanding implantable metallic stent. The stent is made of Nitinol wire weaved in a tubular mesh shape. This structure may make the stent more flexible, compliant and self-expanding. The stent is fully covered with silicone membrane and a polymer coating. The Parylene N is added on the surface of silicone membrane to restrict tumor in-growth through the wire mesh. A retrieval loop made of PE&PP is threaded through the proximal and distal ends of the stent and is intended to aid in removal during the stent placement procedure. The stent has different dimension with the diameters of 10mm, 12mm, 14mm, 16mm, 18mm, with the lengths of 20mm, 30mm, 40mm, 50mm, 60mm, 80mm.

The stent is deployed through the endoscopy working channel and under direct vision of endoscopy. The delivery system allows for desheathing to deploy and reposition the stent during the placement procedure. The delivery system consists of two coaxial sheaths and one inner core. The outer sheath serves to constrain the stent until being retracted during the stent deployment. The middle sheath serves to support the delivery system. The round tip acts as a guide when the delivery system enters the body. The front handle is used for deploying the stent. The seal ring, locking ring, and safe lock work to lock the device and prevent the stent from being exposed. The decoration nut connects with the back handle.

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

The **Through the Scope Tracheal Stent System** incorporates substantially equivalent device materials, design, configuration, packaging fundamental technology, sterilization process and intended use as those featured in the predicate device **Tracheal Stent System (OTW)**.

Comparison to Predicate Devices:

Item	Proposed Device **Through the Scope Tracheal Stent System**	Predicate Device **Tracheal Stent System (OTW) (K202204)**	Remark
Product Code	JCT	JCT	Same
Regulation No.	878.3720	878.3720	Same
Class	2	2	Same
Supplied in Sterile	Yes	Yes	Same
Configuration	Stent and delivery system	Stent and delivery system	Same
Diameter of Stent (mm)	10, 12, 14, 16, 18	10, 12, 14, 16, 18, 20, 22	Similar
Length of Stent (mm)	20, 30, 40, 50, 60, 80	20, 30, 40, 50, 60, 70, 80, 100	Similar
Maximum OD (D) of Delivery System (mm)	2.7	4, 6	Different
Working Length (mm)	1200	650	Different
Covering	Fully Covered	Partially Covered, Fully Covered	Similar
Main Stent material	Nitinol	Nitinol	Same
Main Introduction system materials	PTFE, Pebax, Peek	PTFE, Pebax, Peek	Same
Compatible endoscopy working channel	⩾2.8mm Olympus bronchoscope larger than 2.8mm working channel is recommended.	N/A, the device does not pass through the working channel of endoscopy.	Different
Surgical Technique	The Through the Scope Tracheal Stent System can be directly implanted into the airways through the flexible bronchoscopy	Over the Wire, insert the delivery system through the guidewire	Different

Item	Proposed Device **Through the Scope Tracheal Stent System**	Predicate Device **Tracheal Stent System (OTW) (K202204)**	Remark
	working channel and the deployment is under the direct vision of bronchoscopy.		
Indications for Use	The Through the Scope Tracheal Stent System is indicated for use in the treatment of tracheobronchial strictures caused by malignant neoplasms.	The Tracheal Stent System (OTW) is indicated for use in the treatment of tracheobronchial strictures caused by malignant neoplasms.	Same
Stent function	Maintaining tracheal luminal patency in tracheal strictures	Maintaining tracheal luminal patency in tracheal strictures	Same
Principle of operation	The proposed device consists of the stent and delivery system. The outer sheath of the delivery system serves to constrain the stent before deployment. Loosen the safe lock, then withdraw the front handle to deploy the stent.	The proposed device consists of the stent and delivery system. The outer sheath of the delivery system serves to constrain the stent before deployment. Loosen the safe lock, then withdraw the front handle to deploy the stent.	Same
Single Use	Yes	Yes	Same
Packaging	Single-use EO sterilized blister with one device per blister	Single-use EO sterilized blister with one device per blister	Same
Shelf Life	Two years	Two years	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
Labeling	Conform to 21 CFR part 801	Conform to 21 CFR part 801	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

The proposed device Through the Scope Tracheal Stent System is similar in design to Tracheal Stent System (OTW), which consists of a flexible delivery system preloaded with a self-expanding implantable metallic stent. Both stents are made of Nitinol wire by fabricating as a single, integral

framework tube and a covering is applied to the surface of the stent.

The dimensions of proposed device are covered within the range of that of the predicate device. All comparative non-clinical performance testing have been tested and have met the requirements of substantial equivalence to the predicate device. Both the proposed device and predicated device is EO sterilized and has a two-year shelf life. After EO sterilized and aging, the bench testing and sterility testing of the proposed device meet the requirements of substantial equivalence to the predicate device.

Therefore, the difference between proposed device and predicated device is considered not to affect substantial equivalence between the proposed and predicate devices concerning safety and effectiveness.

8. Performance Data

The biocompatibility evaluation for the Through the Scope Tracheal 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 (issued on September 4, 2020,) the following tests were conducted:

Stent Biocompatibility Testing:

a) Vitro Cytotoxicity
b) Skin Sensitization
c) Irritation
d) Acute Systemic Toxicity
e) Pyrogen
f) Muscle Implant
g) Chemical Characterization and Biological Risk Assessment

Delivery System Biocompatibility Testing:

a) Vitro Cytotoxicity
b) Skin Sensitization

c) 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 and evaluated for the subject device:

a) Dimension Testing

b) Silicone Thickness Test

c) Expansion Force Testing

d) Compression and Recoil Testing

e) Deployment Force Testing

f) Deployment Accuracy and Damage Testing

g) Dislodgement Testing

h) Migration Force and Removability Testing

i) Tensile Strength Testing

j) Repositioning Testing

k) Corrosion Testing

l) Fatigue testing

m) Austenite Finish Temperature Testing:

Shelf-life testing and packaging integrity 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 and ISO 11607-1:2019: Packaging for terminally sterilized medical devices - Part 1: Requirements for materials, sterile barrier systems and packaging systems and ISO 11607-2: 2019: Packaging for terminally sterilized medical devices - Part 2: Validation requirements for forming, sealing and assembly processes. 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+A1:2018 “Sterilization of Health Care products - Ethylene Oxide - Part 1: Requirements for Development, Validation, and

Routine Control of Sterilization processes for Medical Devices".

MR compatibility was evaluated in accordance with ASTM F 2052-15 Standard Test Method for Measurement of Magnetically Induced Displacement Force on Medical Devices in the Magnetic Resonance Environment, ASTM F2182-19e2 Standard Test Method for Measurement of Radio Frequency Induced Heating On or Near Passive Implants During Magnetic Resonance Imaging, ASTM F2119-07(2013)Standard Test Method for Evaluation of MR Image Artifacts from Passive Implants, ASTM F2213-17 Standard Test Method for Measurement of Magnetically Induced Torque on Medical Devices in the Magnetic Resonance Environment, ASTM F2503 - 13 Standard Practice for Marking Medical Devices and Other Items for Safety in the Magnetic Resonance Environment and FDA guidance on Testing and Labeling Medical Devices for Safety in the Magnetic Resonance (MR) Environment issued on May 20, 2021.

The results of all the performance testing demonstrated that the proposed device met the acceptance criteria and support substantial equivalence to the predicate device Tracheal Stent System (OTW) cleared under K202204.

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 **Through the Scope Tracheal Stent System** has been shown to be appropriate for its intended use and is considered to be substantially equivalent to the currently cleared predicate device **Tracheal Stent System (OTW) cleared under K202204**.