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

Re: K212403
Trade/Device Name: Tracheal Stent System (Y-Shaped)
Regulation Number: 21 CFR 878.3720
Regulation Name: Tracheal Prosthesis
Regulatory Class: Class II
Product Code: JCT
Dated: July 30, 2021
Received: August 2, 2021

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)*

K212403

Device Name
Tracheal Stent System (Y-Shaped)

Indications for Use *(Describe)*

The Tracheal Stent System (Y-Shaped) 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: **K212403**

1. Date of Preparation: 2021-10-26

2. Sponsor Identification

Micro-Tech (Nanjing) Co., Ltd.

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Contact Person: Sally He

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3. Identification of Proposed Device

Trade Name: Tracheal Stent System **(**Y-Shaped**)**

Common Name: Tracheal Stent

Regulatory Information

Classification Name: Tracheal Prosthesis

Classification: 2

Product Code: NYT, JCT

Regulation Number: 878.3720

Review Panel: General & Plastic Surgery, Anesthesiology

4. Identification of Predicate Device

Predicate Device

510(k) Number: K971509

Product Name: TRACHEOBRONXANE™ DUMON Tracheo-bronchial Silicone Stent

Manufacturer: Novatech SA

Reference Device

510(k) Number: K140382

Product Name: AERO™ Tracheobronchial Stent Technology System

Manufacturer: Merit Medical Systems, Inc.

As the predicate device only have a Y stent, haven't delivery system, to prove the delivery system of Tracheal Stent System (Y-Shaped) is safe and effective, the reference device AERO™ Tracheobronchial Stent Technology System (K140382) is chosen as the reference device to compare the delivery system.

5. Indications for Use

The Tracheal Stent System (Y-Shaped) is indicated for use in the treatment of tracheobronchial strictures caused by malignant neoplasms.

6. Device Description

The Tracheal Stent System (Y-Shaped) consists of a flexible delivery system preloaded with a self-expanding implantable metallic stent. The stent is made of Nitinol wire by weaving in a Y shaped. This structure design can make the stent more flexible, compliant and self-expanding. The stent is integrated Y-shaped stent, which include 1 main stent, 2 branch stents, the integrated Y-shaped stent can replace three straight shape stents, and the overall design of Y-shaped stent can also be used for the expansion of the carina if there are strictures at the carina. The stent is woven from Nitinol wire. The branch stent is formed with a flange at either end. The stent is partially covered with silicone to restrict tumor in-growth through the wire mesh. To aid in visibility under fluoroscopy

there are radiopaque markers at the stent. There are 3 retrieval loops at the end of stent 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.

7. Comparison of Technological Characteristics

The Tracheal Stent System (Y-Shaped) incorporates substantially equivalent device materials, design, configuration, packaging fundamental technology, sterilization process and intended use as those featured in the predicate device **TRACHEOBRONXANE™ DUMON Tracheo-bronchial Silicone Stent (K971509)**.

Comparison to Predicate Devices:

Item	Proposed Device **Tracheal Stent System (Y-Shaped)**	Predicate Device **TRACHEOBRONXANE™ DUMON Tracheo-bronchial Silicone Stent (K971509)**	Remark
Product Code	NYT, JCT	NWA	Different
Regulation No.	878.3720	878.3720	Same
Class	2	2	Same
Supplied in Sterile	Yes	Yes	Same
Configuration	Stent and delivery system	Stent	Different
Diameter of Stent (mm)	16,18,20,22	14,15,16,18	Different
Diameter of branch stent(mm)	12, 14	10,12,13,14	Different
Length of Stent (mm)	40,50,60	110	Different
Diameter of branch stent(mm)	15,20,30,35	15,20,30,50	Different
Maximum OD (D) of Delivery System (mm)	8	NA, the predicate device haven't delivery system	Different
Working Length (mm)	650		
Covering	Silicone partially covered	Silicone	Different

Item	Proposed Device **Tracheal Stent System (Y-Shaped)**	Predicate Device **TRACHEOBRONXANE™ DUMON Tracheo-bronchial Silicone Stent (K971509)**	Remark
Thickness of Silicone (mm)	0.01-0.20	Unknown	Different
Main Stent material	Nitinol + silicone covering	Silicone	Different
Main Introduction system materials	PTFE, Pebax, Peek, ABS	No delivery system	Different
Compatible endoscopy working channel	N/A, the device does not pass through the working channel of endoscopy.	N/A, the device does not pass through the working channel of endoscopy.	Same
Indications for Use	The Tracheal Stent System is indicated for use in the treatment of tracheobronchial strictures caused by malignant neoplasms.	1.Tracheobronchial tumors 2.Tracheal stenosis with scarring 3.Bronchial stenosis after surgical anastomotic, anastomoses resections or pulmonary transplantation	Similar
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 predicate device only consists of the stent. The deployment of the only Y stent requires rigid bronchoscopy and a transient cessation of ventilation during the procedure.	Different
Single Use	Yes	Yes	Same
Packaging	Single-use EO sterilized blister with one device per blister	Single-use pouch with one device per pouch	Same
Shelf Life	Two years	Five years	Different
Biocompatibility	Conform to ISO 10993-1	Conform to ISO 10993-1	Same
Sterilization	EO Sterilized, SAL:10^{-6}	EO Sterilized, SAL:10^{-6}	Same

Item	Proposed Device **Tracheal Stent System (Y-Shaped)**	Predicate Device **TRACHEOBRONXANE™ DUMON Tracheo-bronchial Silicone Stent (K971509)**	Remark
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 Tracheal Stent System (Y-Shaped) is similar in design and dimension to TRACHEOBRONXANE™ DUMON Tracheo-bronchial Silicone Stent (K971509), both stents are Y-shaped stents, the diameter and length of stent is not exactly the same, but they are very similar, all the performances required for different dimension have been tested and meet the requirement;

The proposed device consists of a flexible delivery system preloaded with the stent, the stent is woven from nitinol wire and a silicone covered. The predicate device only has a silicone Y stent, doesn't include delivery system. For the differences, we choose AERO™ Tracheobronchial Stent Technology System (K140382) as a reference device which consists of a flexible delivery system preloaded with the stent and the stent is nitinol stent and covered with a membrane, the related comparative performance testing to the reference device have been conducted, the test results meet the requirement.

The proposed device is EO sterilized and have a two-years shelf life, the predicate device is sterilized and have a five-years shelf life. After EO sterilized and aging, the bench testing and sterility testing of proposed device meet the requirement.

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

8. Performance Data

The biocompatibility evaluation for the Tracheal Stent System (Y-Shaped) was conducted in accordance with FDA 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

According to the FDA Guidance "Guidance for the content of premarket notifications for esophageal and tracheal prostheses issued April 28th,1998" and the reference device performance, the following performance tests were conducted for the subject device in this premarket submission:

a) Visual Inspection

b) Dimension Testing

c) Deployment Force Testing

d) Expansion Force Testing

e) Compression Force Testing

f) Tensile Strength Testing

g) Guidewire Compatibility Testing

h) Insertion Force

i) Distal Tip Insertion & Flexibility / Kink Resistance Testing

j) Repositioning Force Testing

k) Removal, Migration and Removal Force Testing

l) Fluoroscopic Visibility Testing

m) Endoscopic Visibility Testing

n) Deployment Accuracy Testing

o) Tensile Strength Testing of the Retrieval Loops and Stent

p) Sterility Testing

q) Shelf Life Testing

r) MR Compatibility 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 the 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 predetermined acceptance criteria and is substantial equivalence to the predicate device TRACHEOBRONXANE™ DUMON Tracheo-bronchial Silicone Stent and reference device AERO™ Tracheobronchial Stent Technology System.

9. Animal Test Conclusion

No animal study is included in this submission.

10. Clinical Test Conclusion

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 **Tracheal Stent System (Y-Shaped)** has been shown to be appropriate for its intended use and is considered to be substantially equivalent to the currently cleared predicate device **TRACHEOBRONXANE™ DUMON Tracheo-bronchial Silicone Stent (K971509).**