Micro-Tech (Nanjing) Co., Ltd.
Sally He
RA Engineer
No.10 Gaoke Third Road
Nanjing, 210032 Cn

Re: K202204
Trade/Device Name: Tracheal Stent System (OTW)
Regulation Number: 21 CFR 878.3720
Regulation Name: Tracheal Prosthesis
Regulatory Class: Class II
Product Code: JCT
Dated: July 30, 2020
Received: August 5, 2020

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, PhD
Acting 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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K202204

Device Name
Tracheal Stent System (OTW)

Indications for Use *(Describe)*
The Tracheal Stent System (OTW) 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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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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: **K202204**

1. **Date of Preparation: 2021-09-01**

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

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3. **Identification of Proposed Device**

Trade Name: Tracheal Stent System (OTW)

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: K082284

Product Name: AERO™ Tracheobronchial Stent Technology System

Manufacturer: Merit Medical Systems, Inc.

5. Indications for Use

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

6. Device Description

The Tracheal Stent System (OTW) 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 partially or fully covered with silicone membrane and a polymer coating 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. To aid in visibility under fluoroscopy, there are Tantalum radiopaque markers at the body of the stent. The stent has flanges at the ends to aid in minimizing migration after the stent has been placed in the trachea. The stent has different dimension with the diameter ranging from 10mm, 12mm, 14mm, 16mm, 18mm, 20mm, and 22mm, with the length ranging from 20mm, 30mm, 40mm, 50mm, 60mm, 70mm, 80mm, 90mm, and 100mm.

The delivery system allows for desheathing, to deploy and recapture the stent during stent deployment. The delivery system consists of three coaxial sheaths. 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 inner sheath contains a central lumen that accommodates a 0.035 inch guide wire. The olive tip acts as a guide when the delivery system enters the body along the guide wire. 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. Different diameter delivery systems are applied to different diameter stents. There is an outer sheath diameter of 4 mm and 6 mm and a delivery system with the working length of 650 mm. The 4 mm diameter delivery system is applied to diameter 10 mm stent. The 6 mm diameter delivery system is applied to the 12 mm-22 mm diameter stent. The 6 mm diameter delivery system has one more repositioned function than the 4 mm diameter delivery system. Thus, the 6 mm diameter delivery system has one more positioning piece and visual marker than the 4 mm diameter delivery system. The 6 mm diameter delivery system has four markers and the 4 mm diameter delivery system has three markers. Radiopaque markers at both sheaths and stents can monitor the position under X-ray during the deployment operation.

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 (OTW)** incorporates substantially equivalent device materials, design, configurations, packaging, sterilization processes, and intended use as the predicate device **AERO™ Tracheobronchial Stent Technology System**.

Comparison to predicate Devices:

Item	Proposed Device **Tracheal Stent System (OTW)**	Predicate Device **AERO™ Tracheobronchial Stent Technology System (K082284)**	Remark
Product Code	JCT	JCT	Same
Regulation No.	878.3720	878.3720	Same
Class	2	2	Same
Supplied Sterile	Yes	Yes	Similar
Configuration	Stent and delivery system	Stent and delivery system	Similar
Diameter of Stent (mm)	10,12,14,16,18,20,22	10,12,14,16,18,20	Different
Length of Stent (mm)	20,30,40,50,60,70,80,100	20,30,40,60,80	Different
Maximum OD (D) of Delivery System (mm)	4, 6	5.4, 7.4	Different

Item	Proposed Device **Tracheal Stent System (OTW)**	Predicate Device **AERO™ Tracheobronchial Stent Technology System (K082284)**	Remark
Working Length (mm)	650	560,590,610,620,630	Different
Covering	Partially Covered, Fully Covered	Fully Covered	Different
Main Stent material	Nitinol	Nitinol	Similar
Main Introduction system materials	PTFE, Pebax, Peek	Nylon, PTFE	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.	Similar
Surgical Technique	OTW: Over the Wire, insert the delivery system through the guidewire	Over the Wire (OTW), insert the delivery system through the guidewire	Similar
Indications for Use	The Tracheal Stent System is indicated for use in the treatment of tracheobronchial strictures caused by malignant neoplasms.	The Merit ENDOTEK AERO™ Tracheobronchial Stent System is indicated for use in the treatment of tracheobronchial strictures produced by malignant neoplasms.	Similar
Stent function	Maintaining tracheal luminal patency in tracheal strictures	Maintaining tracheal luminal patency in tracheal strictures	Similar
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 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.	Similar
Single Use	Yes	Yes	Similar
Packaging	Single-use EO sterilized blister with one device per blister	Single-use pouch with one device per pouch	Similar
Shelf Life	Two years	Five years	Different

Item	Proposed Device **Tracheal Stent System (OTW)**	Predicate Device **AERO™ Tracheobronchial Stent Technology System (K082284)**	Remark
Biocompatibility	Conform to ISO 10993-1	Conform to ISO 10993-1	Similar
Sterilization	EO Sterilized, SAL:10^{-6}	Non Sterile	Different
Labeling	Conform to 21 CFR part 801	Conform to 21 CFR part 801	Similar
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	Similar

The proposed device Tracheal Stent System (OTW) is similar in design to AERO™ Tracheobronchial Stent Technology System, 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. Compared with the fully covered predicate device, the proposed device includes partially covered and fully covered configurations. The partially-covered stent is covered in the middle section, with only the flanges at the ends are not covered. The dimensions of proposed device are similar but not identical to the predicate device. All comparative nonclinical performance testing have been tested and have met the requirements of substantial equivalence to the predicate device. The proposed device is EO Sterilized and has a two year shelf life, the predicate device is non-sterilized and five years 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 Tracheal Stent System (OTW) 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) Visual Inspection

b) Dimension Testing

c) Deployment Force and Deployment Accuracy Testing

d) Expansion Force Testing

e) Compression Force Testing

f) Tensile Strength Testing

g) Corrosion Testing

h) Fatigue testing

i) Sterility 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 will be 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 AERO™ Tracheobronchial Stent Technology System.

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 **Tracheal Stent System (OTW)** has been shown to be appropriate for its intended use and is considered to be substantially equivalent to the currently cleared predicate device **AERO™ Tracheobronchial Stent Technology System (K082284)**.