September 21, 2018

Merit Medical Systems, Inc
David Thomas
Principal Regulatory Affairs Specialist
1600 West Merit Parkway
South Jordan, Utah 84095

Re: K181200
Trade/Device Name: AEROmini Tracheobronchial Stent System
Regulation Number: 21 CFR 878.3720
Regulation Name: Tracheal prosthesis
Regulatory Class: Class II
Product Code: JCT
Dated: August 21, 2018
Received: August 22, 2018

Dear David Thomas:

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,

James J. Lee -S

for Tina Kiang, Ph.D.
Acting Director
Division of Anesthesiology,
General Hospital, Respiratory,
Infection Control, and Dental 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K181200

Device Name
AEROmini Tracheobronchial Stent System

Indications for Use *(Describe)*

The Merit ENDOTEK AEROmini™ Tracheobronchial Stent System is indicated for use in the treatment of tracheobronchial strictures produced 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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5.0 510(k) Summary

General Provisions	Correspondent Name: Address: Telephone Number: Fax Number: Contact Person: Date of Preparation: Registration Number:	Merit Medical Systems, Inc. 1600 West Merit Parkway South Jordan, UT 84095 801-316-4956 801-253-6982 David Thomas August 21, 2018 1721504
Subject Device	Trade Name: Common/Usual Name: Classification Name:	AEROmini® Tracheobronchial Stent System Tracheobronchial Stent Tracheal Prosthesis
Predicate Device	Trade Name: Classification Name: Premarket Notification: Manufacturer:	AEROmini™ Tracheobronchial Stent System Tracheal Prosthesis K140382 Merit Medical Systems, Inc.
Classification	Class II 21 CFR § 878.3720 FDA Product Code: JCT Review Panel: Anesthesiology	
Indications For Use	The Merit ENDOTEK AEROmini Tracheobronchial Stent System is indicated for use in the treatment of tracheobronchial strictures produced by malignant neoplasms.	

Device Description	The MERIT ENDOTEK AEROmini Tracheobronchial Stent System is comprised of two components: the radiopaque self-expanding nitinol stent and the delivery system. The stent is completely covered with a biocompatible polyurethane membrane. The stent expansion results from the physical properties of the metal and the proprietary geometry. The overall stent geometry is designed to maintain a constant length over the entire range of possible diameters. As a result of this unique design the stent has virtually no foreshortening, thus facilitating the selection of the appropriate stent length. The stent is deployed endoscopically with a dedicated delivery system with or without the aid of fluoroscopic imaging. The delivery system consists of two coaxial sheaths. The exterior sheath serves to constrain the stent until the sheath is retracted during deployment. The stent remains constrained by the delivery system until the trigger is pulled beyond the white deployment threshold mark located between the trigger and hand grip. This feature allows for repositioning of the stent proximally. A radiopaque tip and marker on the inner shaft aid the operator in determining stent position in relation to the deployment threshold mark, where repositioning or en bloc withdrawal is no longer possible. The inner sheath of the delivery system contains a central lumen that will accommodate a 0.035” guide wire. This feature is designed to allow guidance of the delivery system to the intended implant site while minimizing the risk of airway injury from the delivery system tip. The stent and delivery system are provided sterile using ethylene oxide (EO) process.

Comparison to Predicate Device	The AEROmini is being offered in 6 new size configurations (6 x 10mm, 6x15mm, 8 x 10mm, 10 x10mm, 12 x 10mm, and 14 x 10mm). The current AEROmini has sizes 8x15mm, 8x20mm, 10x15mm, 12x15mm and 14x15mm. The new stents are fabricated as a single, integral framework by laser-cutting a nitinol tube which is the same as the current AEROmini stents. The new stents will be the same as the current AEROmini stents in that a polyurethane polymer cover is applied and a hydrophilic coating is added to the inner diameter surface of the stent. For the 6x10mm and 6x15mm sizes, the ultra-high molecular weight polyethylene/polypropylene suture is attached to a single suture eyelet instead of woven through the eyelets as is done for the other sizes including the currently marketed sizes. The subject and predicate devices are preloaded on a flexible one-handed delivery system. An additional 7.9F delivery system for the 6 mm stents is also added to the current 12F and 16F size delivery systems. New materials (Pebax and Nylon) are used in the 7.9F delivery system for the inner assembly (tubing, marker band and anchor) and outer sheath (pod jacket, flex zone and shaft). This new delivery system allows the stent to be introduced through a 2.8 mm or greater working channel of the bronchoscope. The indications for use of the subject device and predicate device are the same.
Safety & Performance Tests	FDA guidance and recognized performance standards have been established for Tracheal Prosthesis under Section 514 of the Food, Drug and Cosmetic Act. A battery of tests was performed based on the requirements of the below recognized performance standards and guidance, as well as biocompatibility, sterilization, and labeling standards and guidance. Conformity to these standards demonstrates that the proposed AEROmini met the standards' established acceptance criteria applicable to the substantial equivalence of the device. Performance testing was conducted based on the risk analysis and based on the requirements of the following documents: The following tests were successfully conducted as per FDA *Guidance for the Content of Premarket Notifications for Esophageal and Tracheal Prosthesis*, April 28, 1998: Deployment Testing. Expansion Force Testing. Compression Force Testing. Dimensional Testing. Tensile Strength Tests. Guidance for Industry: Guidance for the Content of Premarket Notifications for Esophageal and Tracheal Prostheses (Issued April 28, 1998)

Safety & Performance Tests cont.	*ISO 11135:2014, Sterilization of health care products – routine control of a sterilization process for medical devices* ASTM D4169 –16, Standard Practice for Performance Testing of Shipping Containers and Systems *ASTM F2052-15:2015 Measurement of Magnetically Induced Displacement Force on Medical Devices in the MR Environment* *ASTM F2119-07:2013, Standard Test Method for Evaluation of MR Image Artifacts from Passive Implants* *ASTM F2182-11a:2011, Standard Test Method for Measurement of Radio Frequency Induced Heating Near Passive Implants During MR Imaging* *ASTM F2213-06:2011, Method for Measurement of Magnetically Induced Torque on Medical Devices in MR Environment* *ASTM F2503-08:2013 Marking Medical Devices and Other Items for Safety in the Magnetic Resonance Environment* *ISO 10993-1:2009, Biological Evaluation of Medical Devices - Part 1: Evaluation and Testing within a risk management process, and FDA guidance Required Biocompatibility Training and Toxicology Profiles for Evaluation of Medical Devices, May 1, 1995* ISO 10993-10:2010, *Biological evaluation of medical devices – Part 10: Tests for irritation and skin sensitization* ISO 10993-5:2009*, Biological evaluation of medical devices – Part 5: Tests for in vitro cytotoxicity* ISO 10993-7:2008 - Biological Evaluation of Medical Devices - Part 7: Ethylene Oxide Sterilization Residuals *ISO 10993-11:* 2017, *Biological evaluation of medical devices – Part 11: Tests for systemic toxicity* *ISO11607-1: 2006: Packaging for terminally sterilized medical devices* ISO 2233: 2000 *Packaging — Complete, filled transport packages and unit loads — Conditioning for testing* United States Pharmacopeia 40, National Formulary 35, 2017 <151> Pyrogen Test The following list details significant testing that was successfully completed: Guide Wire Compatibility Delivery Device Working Length Delivery Device Stent Pod OD Delivery Device Shaft OD – 7.9F Trigger Stroke Insertion Force Deployment Force Distal Tip Insertion & Flexibility/Kink Resistance Repositioning Delivery System Deployment Accuracy Stent Expansion & Condition After Deployment System Integrity Stent Foreshortening Removal Stent Dimensions

Safety & Performance Tests cont.	Migration & Removal Force AM-Strut Height Stent Compression Stent Expansion Suture Purse String Stent Dimensions Post Suture Purse String – 12F and 16F only Suture Tensile Strength Stent Tensile Stent Fatigue Cover Integrity After Fatigue Coating Integrity After Fatigue Stent Spring Back After Fatigue Compression Force After Fatigue Expansion Force After Fatigue Delivery System Tensile Strength Tests- 7.9 F only Fluoroscopic Visibility of Deployment Catheter Endoscopic Visibility of Deployment Catheter Atraumatic Tip Compatibility with 2.8mm working channel Compatibility with Olympus BF-1TH190 Rotary Scope MR Compatibility <u>Biocompatibility (for new 7.9F delivery system)</u> Cytotoxicity Sensitization Irritation Material Mediated Pyrogenicity <u>Packaging Performance</u> Seal Peel Strength Visual Inspection Bubble Emission
	The results of the testing demonstrated that the subject AEROmini met the predetermined acceptance criteria applicable to the performance of the device.
Summary of Substantial Equivalence	Based on the indications for use, design, safety and performance testing, the subject AEROmini raises no new questions of safety or effectiveness compared to the predicate device and is substantially equivalent to the predicate device, the AEROmini Tracheobronchial Stent Technology System, K140382 manufactured by Merit Medical Systems, Inc.