DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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November 25, 2014

Merit Medical Systems, Inc.
Dan Lindsay, RAC
Senior Regulatory Affairs Specialist
1600 West Merit Parkway
South Jordan, UT 84095

Re: K140382
Trade/Device Name: AEROmini™ Tracheobronchial Stent System
Regulation Number: 878.3720
Regulation Name: Tracheal Prosthesis
Regulatory Class: Class II
Product Code: JCT
Dated: October 24, 2014
Received: October 27, 2014

Dear Mr. Lindsay,

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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 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 the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Tejashri Purohit-Sheth, M.D.

Tejashri Purohit-Sheth, M.D.
Clinical Deputy Director
DAGRID/ODE/CDRH FOR

Erin I. Keith, M.S.
Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and
Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

4.0 Indications for Use

510(k) Number (if known): K140382

Device Name:

AEROmini™ Tracheobronchial Stent System

Indications for Use:

The MERIT ENDOTEK AEROmini Tracheobronchial Stent System is indicated for use in the treatment of tracheobronchial strictures produced by malignant neoplasms.

Prescription Use ___X___	AND/OR	Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D)		(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE—CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

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 801-208-4408 801-253-6945 Dan W. Lindsay June 3, 2014 1721504
Subject Device	Trade Name: Common/Usual Name: Classification Name:	AEROmini™ Tracheobronchial Stent Tracheal Prosthesis
Predicate Device	Trade Name: Classification Name: Premarket Notification: Manufacturer:	AERO™ Tracheobronchial Stent Technology System Tracheal Prosthesis K082284 Merit Medical Systems, Inc.
Classification	Class II 21 CFR § 878.3720 FDA Product Code: JCT Review Panel: General and Plastic Surgery	
Intended 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. In addition, the procedure can be aborted and the entire system can be withdrawn en bloc at any time before the trigger is pulled beyond the white deployment threshold mark located between the trigger and hand grip. 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.
Comparison to Predicate Device	The AEROmini is similar in design to the AERO Tracheobronchial Stent Technology System. Both stents are fabricated as a single, integral framework by laser-cutting a nitinol tube. A polyurethane polymer cover is then applied and a hydrophilic coating is added to the inner diameter surface of the stent. The subject and predicate devices are preloaded on a flexible one-handed delivery system. The AEROmini is offered in 5 new sizes with diameters as small as 8mm and lengths as short as 15mm. Other stent modifications include: changes to the stent flares, anti-migration struts, new proximal stent end suture eyelets. Changes to the delivery system include: material changes, smaller profile diameter, tapered tip, new trigger safety, and design changes intended to improve ergonomics. The AEROmini will be provided sterile while the predicate was not.

	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.
Performance Tests	Guidance for Industry: Guidance for the Content of Premarket Notifications for Esophageal and Tracheal Prostheses (Issued April 28, 1998) *ISO 11135-1:2007, Sterilization of health care products – routine control of a sterilization process for medical devices* *ASTM D4169 - 09 Standard Practice for Performance Testing of Shipping Containers and Systems* *ASTM F2052-06e1:2006 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 F2182-09:2011, 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 10993-17:2002, Biological evaluation of medical devices – Part 17: Methods for the establishment of allowable limits* *ISO 10993-18:2005, Biological evaluation of medical devices – Part 18: Chemical characterization of materials* *ISO 10993-5:2009, Biological evaluation of medical devices – Part 5: Tests for in vitro cytotoxicity*

Performance Tests cont.	*ISO 10993-6, 2007, Biological Evaluation of Medical Devices - Part 6: Tests for Local Effects After Implantation* *ISO 10993-7:2008, Biological Evaluation of Medical Devices - Part 7: Ethylene Oxide Sterilization Residuals* *ISO11607-1: 2006, Packaging for terminally sterilized medical devices* *United States Pharmacopeia 36, National Formulary 31, 2013. <151> Pyrogen Test* *ISO 2233: 2000, Packaging — Complete, filled transport packages and unit loads — Conditioning for testing* 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 Trigger Stroke Insertion Force Distal Tip Insertion & Flexibility/Kink Resistance Repositioning Delivery System Deployment Accuracy Stent Expansion & Condition After Deployment System Integrity Stent Foreshortening Removal Migration & Removal Force AM-Strut Height Suture Purse String Suture Tensile 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 Trigger Safety Delivery System Tensile Strength Tests Fluoroscopic Visibility of Deployment Catheter Endoscopic Visibility of Deployment Catheter Atraumatic Tip MR Compatibility <u>Biocompatibility</u> Cytotoxicity Sensitization Implantation Irritation Material Mediated Pyrogenicity Chemical Characterization

Performance Tests cont.	Packaging Performance 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 substantial equivalence of the device.
Summary of Substantial Equivalence	Based on the indications for use, design, and performance testing, the subject AEROmini meets the requirements that are considered essential for its intended use and is substantially equivalent to the predicate device, the AERO Tracheobronchial Stent Technology System, K082284.