DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

September 1, 2016

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

Re: K161392
Trade/Device Name: Elation Pulmonary Balloon Dilation Catheter
Regulation Number: 21 CFR 874.4680
Regulation Name: Bronchoscope (Flexible or Rigid) and Accessories
Regulatory Class: Class II
Product Code: KTI
Dated: August 3, 2016
Received: August 4, 2016

Dear Mr. 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. 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 Industry and Consumer Education 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" (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 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 Industry and Consumer Education 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,

Eric A. Mann -S

for Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic and Ear,
Nose and Throat 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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K161392

Device Name
Elation(TM) Pulmonary Balloon Dilation Catheter

Indications for Use *(Describe)*
The Elation™ Pulmonary Balloon Dilation Catheter is intended to be used to endoscopically dilate strictures of the trachea and bronchi.

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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K161392 - 510(k) Summary

General Provisions	Submitter 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 29, 2016 1721504
Subject Device	Trade Name: Common/Usual Name: Classification Name:	Elation™ Pulmonary Balloon Dilation Catheter Pulmonary Balloon Dilation Catheter Bronchoscope (flexible and rigid) and accessories
Predicate Device	Trade Name: Classification Name: Premarket Notification: Manufacturer:	CRE™ Pulmonary Balloon Dilatation Catheter Bronchoscope (flexible and rigid) and accessories K023337 Boston Scientific Corporation
Classification	Class II 21 CFR § 874.4680 FDA Product Code: KTI Review Panel: Ear, Nose & Throat	
Intended Use	The Elation™ Pulmonary Balloon Dilation Catheter is intended to be used to endoscopically dilate strictures of the trachea and bronchi.	

Device Description	The Elation™ Pulmonary Balloon Dilation Catheter is a multi-lumen catheter with a dilation balloon on the distal tip. The catheter is designed to pass through the working channel of an endoscope and accept a 0.035 in (0.89 mm) guidewire through its guidewire lumen. Two redundant inflation lumens are used to inflate and deflate the dilation balloon. The dilation balloon will be available in a 7.5F catheter with a length of 100 cm, balloon lengths of 2.0 cm, 3.0 cm or 5.5 cm and in six balloon diameter ranges from 6 mm to 20 mm. Each balloon size will inflate to three different diameters for the specified inflation pressures. The balloon will be identifiable with both endoscopic and radiopaque marker bands. A glow-in-the-dark tag that can be read in low light conditions is attached to the catheter shaft. The tag indicates diameter and corresponding pressure of the balloon. The balloon will be available in eleven configurations of multiple lengths and diameters. The balloon will be identifiable with both endoscopic and fluoroscopic markers and will be provided sterile.
Comparison to Predicate Device	The Elation™ Pulmonary Balloon Dilation Catheter has the same technological features as the CRE™ Pulmonary Balloon Dilatation Catheter by Boston Scientific Co.(K023337). Both balloons are multistage that come in three distinct diameters ranging from 6 to 20 mm for six balloon sizes. Both catheters pass through a minimum 2.8 mm working channel endoscope. Both systems utilize a 0.035 inch floppy tip guidewire. The balloons for the CRE™ Balloon and the Elation™ Pulmonary Balloon Dilation Catheter are both manufactured from Pebax material. The primary differences are that the Elation™ Pulmonary Balloon Dilation Catheter is available in 2.0 cm, 3.0 cm and 5.5 cm balloon length sizes where the CRE™ Pulmonary Balloon Dilatation Cather has only the 5.5 cm and 3.0 cm sizes and the catheter length for the Elation™ Pulmonary Balloon Dilation Catheter is 100 cm instead of the 75 cm length for which the CRE™ Pulmonary Balloon Dilatation Catheter is available.

Safety & Performance Tests	No performance standards have been established under Section 514 of the Food, Drug and Cosmetic Act for these devices. Performance testing of the subject Elation™ Pulmonary Balloon Dilation Catheter was conducted based on the risk analysis and based on the requirements of the following international standards and guidance documents: *ISO 594-1: 1986 (E) Conical fittings with a 6% (Luer) taper for syringes, needles, and certain other medical equipment – Part 1: General Requirements* *ISO 594-2: 1998 (E) Conical fittings with a 6% (Luer) taper for syringes, needles, and certain other medical equipment – Part 2: Lock fittings* *ISO 10555-1: 2013 – Intravascular catheters – Sterile and single use catheters – Part 1: General Requirements* *ISO 10555-4: 2013 - Intravascular catheters – Sterile and single use catheters - Part 4: Balloon dilatation catheters* *ASTM F 640 – 12 Standard Test Methods for Determining Radiopacity for Medical Use* *Class II Special Controls Guidance Document for Certain Percutaneous Transluminal Coronary Angioplasty (PTCA) Catheters, September 8, 2010.* ISO 11135:2014*, Sterilization of health care products – Ethylene oxide-Requirements for the development, validation and routine control of a sterilization process for medical devices* ISO 10993-1:2009, *Biological Evaluation of Medical Devices Part 1: Evaluation and Testing within a risk management process*. FDA guidance *Required Biocompatibility Training and Toxicology Profiles for Evaluation of Medical Devices*, May 1, 1995 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 10993-10:2010, *Biological evaluation of medical devices – Part 10: Tests for irritation and skin sensitization.*

Safety & Performance Tests cont.

AAMI/ANSI/ISO 11607-1:2006, Packaging for terminally sterilized medical devices – Part 1 – Requirements for materials, sterile barrier systems and packaging systems (Sterility)

ASTM D4169-09, Standards Practice for Performance Testing of Shipping Containers and Systems (Sterility)

ISO 2233 (2000), Packaging – Complete, filled transport packages and unit loads – conditions for testing

Performance Testing-Bench

- Radiopacity
- Tip Perforation
- Guidewire Pushability
- Simulated Bronchoscope Catheter Insertion and Withdrawal
- Balloon Diameter
- Balloon Deflation Time
- Balloon Burst / Freedom from Leakage
- Distal Catheter Joints Tensile
- Proximal Catheter Joints Tensile
- Catheter Pushability
- Catheter Kink
- Kink Recovery
- High Tensile Load Balloon Deflation

Sterilization Validation

The Elation™ Pulmonary Balloon Dilation Catheter will be sterilized using a validated 100% ethylene oxide (EO) sterilization process that is also used for other devices manufactured by Merit, including the predicate device. The EO sterilization cycles employed by Merit Medical are validated by the half cycle / over-kill approach and meet the requirements of ISO 11135:2014 – *Sterilization of health care products – Ethylene oxide-Requirements for the development, validation and routine control of a sterilization process for medical devices.* Validation and annual revalidation have demonstrated a robust program that exceeds the minimum sterility assurance level of 10^{-6} as well as limiting residual sterilant levels to within limits established in EN ISO 10993-7:2008 – Biological Evaluation of Medical Devices, Part 7: Ethylene Oxide Sterilization Residuals.

Biological indicators, which are included with each sterilization lot, are sterility tested as part of the product release process.

Shelf Life Validation

Merit determines shelf life for the packaging and device based on accelerated aging studies conducted according to the Arrhenius Model (Q10). An initial shelf life of 6 months was selected for the subject Elation™ Pulmonary Balloon Dilation Catheter based on the results of the accelerated aging studies. These studies were performed according to approved protocols and procedures following EO sterilization. The accelerated aging testing supported a 6-month shelf life of the product. Upon successful completion of requisite accelerated aging studies, the Elation™ Pulmonary Balloon Dilation Catheter may be labeled with a longer shelf life. Accelerated aging will be supported by real time aging studies which are ongoing.

Packaging Performance

Sterile barrier maintenance was tested after exposure to simulated transportation and storage conditions up to 3 years of accelerated and real time aging. All samples tested passed the tests listed below.

- Seal Peel Strength
- Burst Strength
- Visual Inspection
- Bubble Emission
- Dye Penetration

Biocompatibility

The biocompatibility evaluation for the Elation™ Pulmonary Balloon Dilation Catheter was conducted in accordance with the FDA Blue Book Memorandum #G95-1 “Use of International Standard ISO-10993, ‘Biological Evaluation of Medical Devices Part 1: Evaluation and Testing,’” May 1, 1995, and International Standard ISO 10993-1 “Biological Evaluation of Medical Devices − Part 1: Evaluation and Testing Within a Risk Management Process,” as recognized by FDA. The battery of testing included the following tests:

- Cytotoxicity
- Sensitization
- Irritation

Summary of Substantial Equivalence	Based on the indications for use, design, safety and performance testing, the subject Elation™ Pulmonary Balloon Dilation Catheter meets the requirements that are considered essential for its intended use and is substantially equivalent to the predicate device, the CRE™ Pulmonary Balloon Dilatation Catheter, K023337.