March 8, 2022

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

Re: K213434
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: January 14, 2022
Received: January 18, 2022

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/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,

for Shu-Chen Peng, Ph.D.
Assistant Director
DHT1B: Division of Dental and ENT 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.

Submission Number *(if known)*

K213434

Device Name

Elation™ 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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510(k) #: K213434

510(k) Summary

Prepared on: 2022-01-13

Contact Details

21 CFR 807.92(a)(1)

Applicant Name	Merit Medical Systems, Inc.
Applicant Address	1600 West Merit Parkway South Jordan UT 84095 United States
Applicant Contact Telephone	8013164956
Applicant Contact	Mr. David Thomas
Applicant Contact Email	david.thomas@merit.com

Device Name

21 CFR 807.92(a)(2)

Device Trade Name	Elation™ Pulmonary Balloon Dilation Catheter
Common Name	Bronchoscope (flexible or rigid) and accessories
Classification Name	Bronchoscope Accessory
Regulation Number	874.4680
Product Code	KTI

Legally Marketed Predicate Devices

21 CFR 807.92(a)(3)

Predicate #	Predicate Trade Name (Primary Predicate is listed first)	Product Code
K161392	Elation™ Pulmonary Balloon Dilation Catheter	KTI

Device Description Summary

21 CFR 807.92(a)(4)

The Pulmonary Balloon Catheters are multi-lumen catheters with a dilation balloon on the distal tip. The catheters have two extension legs with luer connectors on the proximal end. The catheter is designed to pass through the working channel of a bronchoscope and accept a 0.035 in (0.89 mm) X 260 cm 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 length of 1.5 cm and in one additional balloon diameter of 4mm range that will be added to the current range 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.

Intended Use/Indications for Use

21 CFR 807.92(a)(5)

The Elation™ Pulmonary Balloon Dilation Catheter is intended to be used to endoscopically dilate strictures of the trachea and bronchi.

Indications for Use Comparison

21 CFR 807.92(a)(5)

The indications for use has not changed from the predicate device.

Technological Comparison

21 CFR 807.92(a)(6)

The Elation® Pulmonary Balloon Dilation Catheter (4mm) size is the same as the currently marketed Elation® Pulmonary Balloon Dilation Catheter except for the smaller diameter range for the balloon of (4-5-6) mm diameter ranges offered and the shorter length of 15mm. The currently marketed Elation® Pulmonary Balloon Dilation Catheter is offered in lengths of 20, 30 and 55mm. There are no changes to the materials, principal of operation or indications for use. It also uses the same 7.5F catheter size with a working length of 100 cm as the current Elation® Pulmonary Balloon Dilation Catheter.

Non-Clinical and/or Clinical Tests Summary & Conclusions

21 CFR 807.92(b)

The following non-clinical tests were performed to support the substantial equivalence for this product:

- Balloon length
- Balloon diameter
- Burst pressure
  - Pressure cycling and leak testing (10 cycles at largest diameter/pressure)
  - Leak testing
  - Material attachment
- Tip Tensile
- Proximal Tensile
- Wire Tensile

In addition, a design validation study was performed with porcine lungs to demonstrate the safety of dilation of smaller (6mm diameter or below) bronchi.

All tests passed the predetermined acceptance criteria.