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

June 23, 2017

Boston Scientific Corporation
Jia Huang
Senior Regulatory Affairs Specialist
100 Boston Scientific Way
Marlborough, MA 01752

Re: K170759
Trade/Device Name: CRE™ Pulmonary Balloon Dilatation Catheter
Regulation Number: 21 CFR 874.4680
Regulation Name: Bronchoscope (flexible or rigid) and accessories
Regulatory Class: Class II
Product Code: KTI
Dated: May 23, 2017
Received: May 24, 2017

Dear Jia Huang:

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,

Denise L. Hampton -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)*
K170759

Device Name
CRE Pulmonary Balloon Dilatation Catheter

Indications for Use *(Describe)*
The CRE Pulmonary Balloon Dilatation Catheter is intended to be used endoscopically to dilate strictures of the airway tree.

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) Summary

1. **Submitter**

Boston Scientific Corporation
100 Boston Scientific Way
Marlborough, MA 01752

Contact: Jia Huang
Sr. Regulatory Affairs Specialist
Email: Jia.Huang@bsci.com
Telephone: (508) 683-4360
Fax: (508) 683-5939

Date Prepared: March 9, 2017

2. **Device**

Trade Name: CRE™ Pulmonary Balloon Dilatation Catheter
Common Name: Balloon Dilatation Catheter
Classification Name: Bronchoscope (flexible and rigid) and accessories
Regulation Number: 21 CFR 874.4680
Product Code: KTI
Classification: Class II

3. **Predicate Device**

Trade Name: CRE™ Pulmonary Balloon Dilatation Catheter
Common Name: Balloon Dilatation Catheter
Manufacturer: Boston Scientific Corporation
Clearance Number: K023337
Classification Name: Bronchoscope (flexible and rigid) and accessories
Regulation Number: 21 CFR 874.4680
Product Code: KTI
Classification: Class II

4. **Reference Device**

Trade Name: Elation™ Pulmonary Balloon Dilatation Catheter
Common Name: Pulmonary Balloon Dilatation Catheter
Manufacturer: Merit Medical Systems, Inc.
Clearance Number: K161392

Classification Name: Bronchoscope (flexible and rigid) and accessories
Regulation Number: 21 CFR 874.4680
Product Code: KTI
Classification: Class II

5. Device Description

The CRE™ Pulmonary Balloon Dilatation Catheter is used to access the airway tree via a bronchoscope for the purpose of dilating strictures. It consists of an inflatable balloon on a catheter shaft with lumens for inflation and passage of a guidewire.

6. Indications for Use

The CRE™ Pulmonary Balloon Dilatation Catheter is intended to be used endoscopically to dilate strictures of the airway tree.

7. Technologies Characteristics

The changes are modifying the design of the CRE™ Pulmonary Balloon Dilatation Catheter to be able to use the device through a flexible bronchoscope working channel by increasing the length of the catheter shaft. The proposed CRE™ Pulmonary Balloon Dilatation Catheter is identical to the predicate CRE™ Pulmonary Balloon Dilatation Catheter (K023337), with the exception of catheter shaft working length.

8. Performance Data

In-Vitro Testing has been performed and all full devices met the required specifications for the completed tests. A summary of the test results has been provided for Kink Resistance, Scope Insertion, Scope Removal, Inflation Time and Deflation Time.

9. Conclusion

Boston Scientific Corporation has demonstrated that the proposed CRE™ Pulmonary Balloon Dilatation Catheter is substantially equivalent to Boston Scientific Corporation's currently marketed CRE™ Pulmonary Balloon Dilatation Catheter (K023337).