July 28, 2022

Boston Scientific Corporation
Carter Navarro
Fellow, Regulatory Affairs
100 Boston Scientific Way
Marlborough, Massachusetts 01752

Re: K222014
Trade/Device Name: EXALT Model B Single-Use Bronchoscope
Regulation Number: 21 CFR 874.4680
Regulation Name: Bronchoscope (Flexible Or Rigid) And Accessories
Regulatory Class: Class II
Product Code: EOQ
Dated: July 7, 2022
Received: July 8, 2022

Dear Carter Navarro:

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.*

510(k) Number *(if known)*
K222014

Device Name
EXALT Model B Single-Use Bronchoscope

Indications for Use *(Describe)*
The EXALT Model B Single-Use Bronchoscope is intended for use with the EXALT Monitor for endoscopic procedures within the airways and tracheobronchial 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.***

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**Boston Scientific Corporation**
Endoscopy Division
100 Boston Scientific Way
Marlborough, MA 01752
(508) 683-4000
www.bostonscientific.com

# 510(k) Summary for EXALT Model B Single-Use Bronchoscope (K222014)

## 1. Submitter

Boston Scientific Corporation
100 Boston Scientific Way
Marlborough, MA 01752

**Contact:** Carter Navarro
Fellow, Regulatory Affairs
Phone: (508) 382-0356
E-mail: carter.navarro@bsci.com

Date Prepared: July 7, 2022

## 2. Device

| | |
|---|---|
| Trade Name: | EXALT Model B Single-Use Bronchoscope (Slim);<br>EXALT Model B Single-Use Bronchoscope (Regular);<br>EXALT Model B Single-Use Bronchoscope (Large); |
| Common Name: | Bronchoscope (flexible or rigid) |
| Product Code: | EOQ |
| Device Class: | Class II |
| Device Panel: | Ear Nose & Throat |
| Classification Regulation: | 21 CFR 874.4680, Bronchoscope (flexible or rigid) and accessories |

## 3. Predicate Device

| | |
|---|---|
| Trade Name: | EXALT Model B Single-Use Bronchoscope (Slim);<br>EXALT Model B Single-Use Bronchoscope (Regular);<br>EXALT Model B Single-Use Bronchoscope (Large); |
| Clearance Number: | K211030 |
| Common Name: | Bronchoscope (flexible or rigid) |
| Product Code: | EOQ |
| Device Class: | Class II |
| Device Panel: | Ear Nose & Throat |
| Classification Regulation: | 21 CFR 874.4680, Bronchoscope (flexible or rigid) and accessories |

## 4. Device Description

The EXALT Model B Single-Use Bronchoscope is a sterile, single-use bronchoscope available in three sizes (Slim, Regular, and Large). The proposed device facilitates examination of the airways and trachea, delivery of accessories (Regular and Large sizes only), and delivery of live video when connected to an EXALT Monitor.

## 5. Indications for Use

The EXALT Model B Single-Use Bronchoscope is intended for use with the EXALT Monitor for endoscopic procedures within the airways and tracheobronchial tree.

## 6. Technological Characteristics

The proposed EXALT Model B Single-Use Bronchoscope is identical to the predicate device.

## 7. Substantial Equivalence

The proposed EXALT Model B Single-Use Bronchoscope is identical to the predicate device. The purpose of this Special 510(k) was to revise the specifications for insertion tube stiffness for the Slim, Regular, and Large sizes of the proposed device. For all three sizes, the upper end of the two-sided specification was increased. The new specifications were set based on test results from new, unopened samples of the original predicate device (Ambu aScope 4 Broncho, K173727) to which the EXALT Model B Single-Use Bronchoscope was shown to be substantially equivalent in the original premarket notification (K211030).

## 8. Performance Data

Performance testing was not required to establish a finding of substantial equivalence between the proposed device and the predicate device, since the device is unchanged. Performance testing was conducted on new, unopened samples of the original predicate device (Ambu aScope 4 Broncho, K173727) to establish the insertion tube stiffness seen in commercial use.

## 9. Conclusion

Boston Scientific has demonstrated that the proposed EXALT Model B Single-Use Bronchoscope is substantially equivalent to the currently marketed predicate device.