August 9, 2021

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

Re: K211030
Trade/Device Name: EXALT Model B Single-Use Bronchoscope (Slim), EXALT Model B Single-Use Bronchoscope (Regular), EXALT Model B Single-Use Bronchoscope (Large), EXALT Monitor
Regulation Number: 21 CFR 874.4680
Regulation Name: Bronchoscope (Flexible Or Rigid) And Accessories
Regulatory Class: Class II
Product Code: EOQ
Dated: July 8, 2021
Received: July 9, 2021

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
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)*

K211030

Device Name

EXALT Model B Single-Use Bronchoscope; EXALT Monitor

Indications for Use *(Describe)*

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

EXALT Monitor:
The EXALT Monitor is intended for use with a Boston Scientific single-use endoscope for endoscopic diagnosis, treatment, and video observations.

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.

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510(k) Summary for EXALT Bronchoscopic Visualization System (EXALT Model B Single-Use Bronchoscope and EXALT Monitor)

1. Submitter

Boston Scientific Corporation
Endoscopy Division
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: April 5, 2021

2. Device

Trade Name:	EXALT Model B Single-Use Bronchoscope (Slim); EXALT Model B Single-Use Bronchoscope (Regular); EXALT Model B Single-Use Bronchoscope (Large) EXALT Monitor
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 Devices

Trade Name:	Ambu aScope 4 Broncho Slim 3.8/1.2 Ambu aScope 4 Broncho Regular 5.0/2.2 Ambu aScope 4 Broncho Large 5.8/2.8 Ambu aView Monitor
Manufacturer:	Ambu A/S
Clearance Number:	K173727
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.

The EXALT Monitor is an electronic device that:

- Receives video signals from a Boston Scientific single-use endoscope,
- Processes the video signals,
- Displays image on integrated display
- Outputs video images to a secondary video monitor when connected to AC mains,
- Outputs electrical signal(s) that interface with external image capture systems, and
- Saves and exports procedure images and videos.

The EXALT Monitor also controls the light transmitted by the tip of the single-use endoscope to illuminate the area of interest within the anatomy. Buttons on the Monitor touch screen enable the user to control the brightness level of the light.

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.

The EXALT Monitor is intended for use with a Boston Scientific single-use endoscope for endoscopic diagnosis, treatment, and video observations.

6. Technological Characteristics

The proposed EXALT Model B Single-Use Bronchoscope and EXALT Monitor share similar design features and functions with their respective predicate devices.

The EXALT Model B Single-Use Bronchoscope and Ambu aScope 4 Broncho share similar mechanical and optical characteristics, including working length, diameters, articulation angles, resolution, direction of view, and field of view. Suction rates of the proposed device are equivalent or superior to those of the predicate device. Both devices

are available in three sizes (Slim, Regular, and Large). Both devices are sterile, single-use, and not intended for reprocessing.

Item	Subject Device EXALT Model B Single-Use Bronchoscope	Predicate Device Ambu aScope 4 Broncho
Field of View	90°	85°
Direction of View	0°	0°
Depth of Field	6-50 mm	6-50 mm
Working Length	60 cm	60 cm
Articulation Angle	Slim: 180° up, 180° down Regular: 180° up, 180° down Large: 180° up, 180° down	Slim: 180° up, 180° down Regular: 180° up, 180° down Large: 180° up, 160° down
Insertion Tube Outer Diameter	Slim: 3.8 mm Regular: 5.0 mm Large: 5.8 mm	Slim: 3.8 mm Regular: 5.0 mm Large: 5.8 mm
Insertion Portion Maximum Diameter	Slim: 4.3 mm Regular: 5.5 mm Large: 6.3 mm	Slim: 4.3 mm Regular: 5.5 mm Large: 6.3 mm
Minimum Working Channel Diameter	Slim: 1.0 mm Regular: 2.0 mm Large: 2.6 mm	Slim: 1.2 mm Regular: 2.0 mm Large: 2.6 mm
Average Working Channel Diameter	Slim: 1.2 mm Regular: 2.2 mm Large: 2.8 mm	Slim: 1.2 mm Regular: 2.2 mm Large: 2.8 mm
Minimum ETT Inner Diameter Size	Slim: 5.0 mm Regular: 6.0 mm Large: 7.0 mm	Slim: 5.0 mm Regular: 6.0 mm Large: 7.0 mm
Minimum DLT Inner Diameter Size	Slim: 35 Fr Regular: 41 Fr Large: N/A	Slim: 35 Fr Regular: 41 Fr Large: N/A

The EXALT Monitor and Ambu aView Monitor share similar physical and display specifications and similar controls for the respective visualization devices with which they are used.

Item	Subject Device EXALT Monitor	Predicate Device Ambu aView Monitor
Maximum resolution	2736 x 1824	800 x 480
Orientation	Landscape	Landscape
Display Size	12.3”	8.5”
Brightness control	Yes	Yes
Contrast control	No	Yes
Storage	85 GB	8 GB
Battery Life	1.5 hours	3 hours
Operating Environment (Temperature)	10 - 33°C	10 - 40°C
Operating Environment (Humidity)	30 - 85%	30 - 85%
Operating Environment (Pressure)	700 - 1090 hPa	800 - 1090 hPa
Dimensions (W x H x D)	13.6” x 8.4” x 2.3”	9.49” x 6.89” x 1.32”
Weight	4.7 lbs.	3.31 lbs.

7. Substantial Equivalence

A direct comparison of key characteristics demonstrates that the EXALT Model B Single-Use Bronchoscope and EXALT Monitor are substantially equivalent to their respective currently marketed predicate devices in terms of intended use, technological characteristics, and performance characteristics. The EXALT Model B Single-Use Bronchoscope and EXALT Monitor are substantially equivalent to the currently marketed predicate devices.

8. Performance Data

Non-clinical testing was successfully performed on the proposed EXALT Model B Single-Use Bronchoscope and EXALT Monitor.

Performance testing (bench) was successfully completed to establish substantial equivalence between the proposed EXALT Model B Single-Use Bronchoscope and EXALT Monitor and the predicate devices. This testing included the following:

- Insertion Portion Width
- Working Channel Width
- Working Length
- Field of View
- Direction of View
- Articulation Angles
- Suction Rate
- Resolution
- Light Output
- Durability
- Photobiological Safety
- Image Intensity Uniformity
- Geometric Distortion
- Noise
- Dynamic Range
- Color Performance

Applicable performance requirements were evaluated in accordance with the ISO 8600 series. Biocompatibility of the EXALT Model B Single-Use Bronchoscope was evaluated in accordance with ISO 10993-1. Electrical safety and electromagnetic compatibility of the EXALT Model B Single-Use Bronchoscope and EXALT Monitor were evaluated in accordance with AAMI / ANSI ES60601-1, IEC 60601-1-2, and IEC 60601-2-18.

The results of non-clinical testing demonstrate that the EXALT Model B Single-Use Bronchoscope and EXALT Monitor are substantially equivalent to the currently marketed predicate devices.

9. Conclusion

Boston Scientific has demonstrated that the proposed EXALT Model B Single-Use Bronchoscope and EXALT Monitor are substantially equivalent to the currently marketed predicate devices.