

**K211030 EXALT Model B Single-Use Bronchoscope (Slim),  
EXALT Model B Single-Use Bronchoscope (Regular), EXALT  
Model B Single-Use Bronchoscope (Large), EXALT Monitor**Aug 9, 2021  
125 days to decisionK211030 · Product code: **EOQ** · Ear, Nose, Throat  
Source: <https://www.510kdatabase.net/k211030/>**SUBMISSION DETAILS**

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|                       |  |
|-----------------------|--|
| Decision              | Substantially Equivalent (Cleared)     |
| Submission type       | Traditional                            |
| Device classification | Bronchoscope (flexible Or Rigid) (EOQ) |
| Date received         | Apr 6, 2021                            |
| Decision date         | Aug 9, 2021                            |
| Days to decision      | 125 days                               |
| Third-party review    | No                                     |
| Combination product   | No                                     |
| PCCP authorized       | No                                     |
| Summary / Statement   | Summary                                |

**APPLICANT**

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|----------------|---|
| Company        | <b>Boston Scientific Corporation</b>  |
| Location       | Marlborough, MA, US   |
| Contact        | Carter Navarro  |
| Website        | <a href="https://www.bostonscientific.com">https://www.bostonscientific.com</a> |
| 510(k) history | 229 submissions · 216 cleared · 2005-2026                                       |

Boston Scientific Corporation is a global medical device manufacturer headquartered in Marlborough, Massachusetts. The company develops and markets devices across multiple medical specialties. Boston Scientific has received FDA 510(k) clearances from total submissions since its first clearance in 2005. The company maintains active regulatory engagement, with the latest clearance in 2026. Its cleared devices span cardiovascular, radiology, gastroenterology, urology, and surgical specialties, reflecting a broad portfolio of interventional and diagnostic technologies. Recent...