

**K210833 Portex BLUxl Extra Length Tracheostomy Tube, BLUxl Suctionaid Extra Length Tracheostomy Tube, BLUxl Extra Length Tracheostomy Inner Cannula**Nov 26, 2021  
252 days to decisionK210833 · Product code: **JOH** · Anesthesiology  
Source: <https://www.510kdatabase.net/k210833/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Tube Tracheostomy And Tube Cuff (JOH)
Date received	Mar 19, 2021
Decision date	Nov 26, 2021
Days to decision	252 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Smiths Medical Asd, Inc.</b>
Location	Rockland, MA, US
Contact	Nancy DeAngelo
510(k) history	52 submissions · 52 cleared · 2004-2024

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k210833/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](https://accessdata.fda.gov)).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at [accessdata.fda.gov](https://accessdata.fda.gov). - Generated May 13, 2026