

**K083641 BIVONA TRACHEOSTOMY TUBES**Feb 23, 2009  
76 days to decisionK083641 · Product code: **JOH** · Anesthesiology  
Source: <https://www.510kdatabase.net/k083641/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Tube Tracheostomy And Tube Cuff (JOH)
Date received	Dec 9, 2008
Decision date	Feb 23, 2009
Days to decision	76 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Smiths Medical Asd, Inc.</b>
Location	Rockland, MA, US
Contact	DANIEL COATES
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/k083641/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://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](http://accessdata.fda.gov). - Generated May 24, 2026