

**K922665 BIVONA HYPERFLEX TRACHEOSTOMY TUBE**Jan 7, 1993  
220 days to decisionK922665 · Product code: **JOH** · Anesthesiology  
Source: <https://www.510kdatabase.net/k922665/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Tube Tracheostomy And Tube Cuff (JOH)
Date received	Jun 1, 1992
Decision date	Jan 7, 1993
Days to decision	220 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Bivona Medical Technologies</b>
Location	Mchenry, IL, US
Contact	HARRY KAUFMAN
510(k) history	50 submissions · 50 cleared · 1978-1995

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k922665/> 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 26, 2026