

**K920604 BIVONA TRACHEAL T-TUBE STENT**Jul 27, 1992  
167 days to decisionK920604 · Product code: **BTO** · Anesthesiology  
Source: <https://www.510kdatabase.net/k920604/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Tube, Tracheostomy (w/wo Connector) (BTO)
Date received	Feb 11, 1992
Decision date	Jul 27, 1992
Days to decision	167 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 M 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/k920604/> 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