

**K954197 DISPOSABLE FLEX TUBE**Oct 26, 1995  
50 days to decisionK954197 · Product code: **BZA** · Anesthesiology  
Source: <https://www.510kdatabase.net/k954197/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Connector, Airway (extension) (BZA)
Date received	Sep 6, 1995
Decision date	Oct 26, 1995
Days to decision	50 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Engstrom Medical</b>
Location	Sturgis, MI, US
Contact	WULF TREPTE
510(k) history	2 submissions · 2 cleared · 1995-1995

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k954197/> 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