

**K160127 iCodeConnect**Nov 10, 2016  
295 days to decisionK160127 · Product code: **BZD** · Anesthesiology  
Source: <https://www.510kdatabase.net/k160127/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Ventilator, Non-continuous (respirator) (BZD)
Date received	Jan 20, 2016
Decision date	Nov 10, 2016
Days to decision	295 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>3B Medical, Inc.</b>
Location	Lake Wales, FL, US
Contact	ALEX LUCIO
510(k) history	10 submissions · 10 cleared · 2013-2022

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k160127/> 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 27, 2026