

**K103434 3B FLEX-LITE**Oct 13, 2011  
324 days to decisionK103434 · Product code: **BZD** · Anesthesiology  
Source: <https://www.510kdatabase.net/k103434/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Ventilator, Non-continuous (respirator) (BZD)
Date received	Nov 23, 2010
Decision date	Oct 13, 2011
Days to decision	324 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>3B Products, LLC</b>
Location	Lake Wales, FL, US
Contact	ALBERT ALEXANDER LUCIO
510(k) history	2 submissions · 2 cleared · 2011-2012

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k103434/> 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