

**K043495 BABYPAC**Apr 22, 2005  
126 days to decisionK043495 · Product code: **BTL** · Anesthesiology  
Source: <https://www.510kdatabase.net/k043495/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Ventilator, Emergency, Powered (resuscitator) (BTL)
Date received	Dec 17, 2004
Decision date	Apr 22, 2005
Days to decision	126 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Smiths Medical International Ltd., Luton</b>
Location	Waukesha, WI, US
Contact	DONALD ALEXANDER
510(k) history	1 submissions · 1 cleared · 2005-2005

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k043495/> 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 25, 2026