

**K053168 BIPAP FOCUS**Jan 4, 2006  
51 days to decisionK053168 · Product code: **MNS** · AnesthesiologySource: <https://www.510kdatabase.net/k053168/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Ventilator, Continuous, Non-life-supporting (MNS)
Date received	Nov 14, 2005
Decision date	Jan 4, 2006
Days to decision	51 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Respironics (Ireland) Limited</b>
Location	Galway, IE
Contact	JOHN O'NEILL;DEA
510(k) history	1 submissions · 1 cleared · 2006-2006

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k053168/> 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