

**K103631 SLEEPMINDER BREATHING FREQUENCY INDICATOR**Jul 21, 2011  
220 days to decisionK103631 · Product code: **BZQ** · Anesthesiology  
Source: <https://www.510kdatabase.net/k103631/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Monitor, Breathing Frequency (BZQ)
Date received	Dec 13, 2010
Decision date	Jul 21, 2011
Days to decision	220 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Biancamed Limited</b>
Location	Belfield, Dublin, IE
Contact	PAUL PHILLIPS
510(k) history	1 submissions · 1 cleared · 2011-2011

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k103631/> 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