

**K012368 AEROPEP**Feb 12, 2002  
201 days to decisionK012368 · Product code: **BWF** · Anesthesiology  
Source: <https://www.510kdatabase.net/k012368/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Spirometer, Therapeutic (incentive) (BWF)
Date received	Jul 26, 2001
Decision date	Feb 12, 2002
Days to decision	201 days
Third-party review	No
Summary / Statement	Statement

**APPLICANT**

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Company	<b>Trudell Medical Intl.</b>
Location	London, CA
Contact	TOM HOLBROOK
510(k) history	12 submissions · 12 cleared · 2002-2013

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k012368/> 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