

**K091428 EASYONE PRO RESPIRATORY ANALYSIS SYSTEM**Jan 27, 2010  
258 days to decisionK091428 · Product code: **BTY** · Anesthesiology  
Source: <https://www.510kdatabase.net/k091428/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Calculator, Predicted Values, Pulmonary Function (BTY)
Date received	May 14, 2009
Decision date	Jan 27, 2010
Days to decision	258 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Ndd Medizitechnik AG</b>
Location	Andover, MA, US
Contact	GERARD MASIELLO
510(k) history	3 submissions · 3 cleared · 2009-2012

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k091428/> 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