

**K161534 EasyOne Pro Respiratory Analysis System**Feb 22, 2017  
264 days to decisionK161534 · Product code: **BTY** · Anesthesiology  
Source: <https://www.510kdatabase.net/k161534/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Calculator, Predicted Values, Pulmonary Function (BTY)
Date received	Jun 3, 2016
Decision date	Feb 22, 2017
Days to decision	264 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Ndd Medizintechnik AG</b>
Location	Zurich, CH
Contact	N/A N/A
510(k) history	4 submissions · 4 cleared · 2017-2023

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k161534/> 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