

**K230178 EasyOne Sky Spirometer**Oct 19, 2023  
269 days to decisionK230178 · Product code: **BZG** · Anesthesiology  
Source: <https://www.510kdatabase.net/k230178/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Spirometer, Diagnostic (BZG)
Date received	Jan 23, 2023
Decision date	Oct 19, 2023
Days to decision	269 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Ndd Medizintechnik AG</b>
Location	Zurich, CH
Contact	Andreas Senn
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/k230178/> 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