

**K171235 OmniCap**Jan 4, 2018  
252 days to decisionK171235 · Product code: **CCK** · Anesthesiology  
Source: <https://www.510kdatabase.net/k171235/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Analyzer, Gas, Carbon-dioxide, Gaseous-phase (CCK)
Date received	Apr 27, 2017
Decision date	Jan 4, 2018
Days to decision	252 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Respirion, Inc.</b>
Location	Winston-Salem, NC, US
Contact	Ed Fadel
510(k) history	1 submissions · 1 cleared · 2018-2018

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k171235/> 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