

**K122290 ENVITEC MYSIGN O OXYGEN MEASURING DEVICE**Jan 23, 2013  
177 days to decisionK122290 · Product code: **CCL** · Anesthesiology  
Source: <https://www.510kdatabase.net/k122290/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Analyzer, Gas, Oxygen, Gaseous-phase (CCL)
Date received	Jul 30, 2012
Decision date	Jan 23, 2013
Days to decision	177 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Envitec-Wismar GmbH</b>
Location	Egale, WI, US
Contact	STEPHEN GORSKI
510(k) history	9 submissions · 9 cleared · 2000-2014

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k122290/> 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