

**K082655 ENVITEC MEDICAL OXYGEN SENORS, MODELS
OOM101**Nov 25, 2008
74 days to decisionK082655 · Product code: **CCL** · Anesthesiology
Source: <https://www.510kdatabase.net/k082655/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Analyzer, Gas, Oxygen, Gaseous-phase (CCL)
Date received	Sep 12, 2008
Decision date	Nov 25, 2008
Days to decision	74 days
Third-party review	No
Summary / Statement	Summary
Other names	00M102/-1;OOM103/-1/-1M;OOM104;OOM105;OOM106

APPLICANT

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k082655/> Data sourced from FDA 510(k) public records (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. - Generated May 24, 2026