

**K143216 Assurance Alar / Nasal SpO2 Sensor**Mar 17, 2015  
127 days to decisionK143216 · Product code: **DQA** · Anesthesiology  
Source: <https://www.510kdatabase.net/k143216/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Oximeter (DQA)
Date received	Nov 10, 2014
Decision date	Mar 17, 2015
Days to decision	127 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Xhale, Inc.</b>
Location	Gainesville, FL, US
Contact	Jeffrey Hoebelheinrich
510(k) history	2 submissions · 2 cleared · 2015-2017

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k143216/> 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