

**K233827 OxiWear**Aug 28, 2024  
271 days to decisionK233827 · Product code: **DQA** · Anesthesiology  
Source: <https://www.510kdatabase.net/k233827/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Oximeter (DQA)
Date received	Dec 1, 2023
Decision date	Aug 28, 2024
Days to decision	271 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Oxiwear, Inc.</b>
Location	Arlington, VA, US
Contact	Shavini Fernando
510(k) history	1 submissions · 1 cleared · 2024-2024

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k233827/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](https://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](https://accessdata.fda.gov). - Generated May 14, 2026