

**K182887 Masimo Rad-67 Pulse CO-Oximeter and Accessories**Mar 22, 2019  
158 days to decisionK182887 · Product code: **DQA** · Anesthesiology  
Source: <https://www.510kdatabase.net/k182887/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Oximeter (DQA)
Date received	Oct 15, 2018
Decision date	Mar 22, 2019
Days to decision	158 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Masimo Corporation</b>
Location	Irvine, CA, US
Contact	Sindura Penubarthi
Website	<a href="http://www.masimo.com/">http://www.masimo.com/</a>
510(k) history	84 submissions · 82 cleared · 2004-2025

Masimo Corporation is an American health technology and consumer electronics company headquartered in Irvine, California. The company develops patient monitoring devices, non-invasive sensors, and related software platforms for hospital and home settings. Masimo has received FDA 510(k) clearances from total submissions since its first clearance in 2004. The company's regulatory focus centers on Anesthesiology devices, which represent 74% of submissions. Latest clearance activity in 2025 demonstrates continued regulatory engagement. Recent cleared devices span Anesthesiolo...

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