

**K181956 Masimo MightySat Rx Fingertip Pulse Oximeter**Jan 23, 2019  
184 days to decisionK181956 · Product code: **DQA** · Anesthesiology  
Source: <https://www.510kdatabase.net/k181956/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Oximeter (DQA)
Date received	Jul 23, 2018
Decision date	Jan 23, 2019
Days to decision	184 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Masimo Corporation</b>
Location	Irvine, CA, US
Contact	Kelly Nguyen
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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