

**K162603 Masimo O3 Regional Oximeter System**May 26, 2017  
249 days to decisionK162603 · Product code: **MUD** · Cardiovascular  
Source: <https://www.510kdatabase.net/k162603/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Oximeter, Tissue Saturation (MUD)
Date received	Sep 19, 2016
Decision date	May 26, 2017
Days to decision	249 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Masimo Corporation</b>
Location	Irvine, CA, US
Contact	MARGUERITE THOMLINSON
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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