

K182429 Masimo O3 Regional Oximeter SystemJun 7, 2019
274 days to decisionK182429 · Product code: **MUD** · Neurology
Source: <https://www.510kdatabase.net/k182429/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Oximeter, Tissue Saturation (MUD)
Date received	Sep 6, 2018
Decision date	Jun 7, 2019
Days to decision	274 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Masimo Corporation
Location	Irvine, CA, US
Contact	Sindura Penubarthi
Website	http://www.masimo.com/
510(k) history	85 submissions · 83 cleared · 2004-2026

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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Device record: <https://www.510kdatabase.net/k182429/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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