

K214115 MightySat -OTCJan 31, 2024
762 days to decisionK214115 · Product code: **OLK** · Anesthesiology
Source: <https://www.510kdatabase.net/k214115/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Pulse Oximeter For Over-the-counter Use (OLK)
Date received	Dec 30, 2021
Decision date	Jan 31, 2024
Days to decision	762 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Masimo Corporation
Location	Irvine, CA, US
Contact	Kertana Shankar
Website	http://www.masimo.com/
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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Device record: <https://www.510kdatabase.net/k214115/>; Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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