FDA 510(k) Premarket Notification

CLEARED

K243324 Masimo O3 Regional Oximeter

Jul 17, 2025
267 days to decision

K243324 · Product code: **MUD** · General & Plastic Surgery
Source: https://www.510kdatabase.net/k243324/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Oximeter, Tissue Saturation (MUD)
Date received	Oct 23, 2024
Decision date	Jul 17, 2025
Days to decision	267 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...

CLINICAL EVIDENCE - NCT03396835

Desaturation Validation of INVSENSOR00009

Status	Completed
Enrollment	16 patients (actual)
Study sites	1 site
Condition studied	Healthy
Primary purpose	Other
Study type	Interventional
Study design	Single group
Masking	Open label
Completion date	Jan 16, 2018
Sponsor	Masimo Corporation (Industry)

Primary outcome

Trending Regional Oxygen Saturation Accuracy of the INVSENSOR00009 Relative to the Control Sensor by Arms Calculation

Source: ClinicalTrials.gov / U.S. National Library of Medicine - clinicaltrials.gov/study/NCT03396835