

K094046 LNCS OXIMETRY SENSORS, REPROCESSED LNCS OXIMETRY SENSORSMay 14, 2010
134 days to decisionK094046 · Product code: **DQA** · Anesthesiology
Source: <https://www.510kdatabase.net/k094046/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Oximeter (DQA)
Date received	Dec 31, 2009
Decision date	May 14, 2010
Days to decision	134 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Masimo Corporation
Location	Irvine, CA, US
Contact	MARGUERITE THOMLINSON
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...

510k Database - www.510kdatabase.net

Device record: <https://www.510kdatabase.net/k094046/>. Data sourced from FDA 510(k) public records (accessdata.fda.gov).

510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated May 24, 2026