FDA 510(k) Premarket Notification

K111621 MASIMO RESPOSABLE SPO2 SERIES OXIMETRY SENSORS, MASIMO LNCS / M-LNCS OXIMETRY SENSORS

CLEARED

Oct 26, 2011
138 days to decision

K111621 · Product code: **DQA** · Anesthesiology
Source: https://www.510kdatabase.net/k111621/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Oximeter (DQA)
Date received	Jun 10, 2011
Decision date	Oct 26, 2011
Days to decision	138 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Masimo Corporation**
Location	Irvine, CA, US
Contact	ANIL BHALANI
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...