FDA 510(k) Premarket Notification

CLEARED

K151644 Masimo Root Vital Signs Monitoring System and Accessories

Feb 12, 2016
239 days to decision

K151644 · Product code: **MWI** · Cardiovascular
Source: https://www.510kdatabase.net/k151644/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Monitor, Physiological, Patient (without Arrhythmia Detection Or Alarms) (MWI)
Date received	Jun 18, 2015
Decision date	Feb 12, 2016
Days to decision	239 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/k151644/ Data sourced from FDA 510(k) public records (accessdata.fda.gov).
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