FDA 510(k) Premarket Notification

CLEARED

K162675 Masimo Rainbow SET Intellivue Module Pulse CO-Oximeter

Dec 28, 2016
93 days to decision

K162675 · Product code: **DQA** · Anesthesiology
Source: https://www.510kdatabase.net/k162675/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Oximeter (DQA)
Date received	Sep 26, 2016
Decision date	Dec 28, 2016
Days to decision	93 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...