FDA 510(k) Premarket Notification

K073024 MASIMO RAINBOW SET RAD 87 PULSE CO-OXIMETER AND ACCESSORIES

CLEARED

Feb 8, 2008
105 days to decision

K073024 · Product code: **DQA** · Anesthesiology
Source: https://www.510kdatabase.net/k073024/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Oximeter (DQA)
Date received	Oct 26, 2007
Decision date	Feb 8, 2008
Days to decision	105 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...