

K091241 MASIMO RAINBOW SET RADICAL 7 PULSE CO-OXIMETERNov 6, 2009
193 days to decisionK091241 · Product code: **DQA** · Anesthesiology
Source: <https://www.510kdatabase.net/k091241/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Oximeter (DQA)
Date received	Apr 27, 2009
Decision date	Nov 6, 2009
Days to decision	193 days
Third-party review	No
Summary / Statement	Summary
Other names	RAD 87 PULSE CO-OXIMETER

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...