FDA 510(k) Premarket Notification

K100617 MASIMO RESPONSABLE OXIMETRY SENSORS MODEL S2-25/25D

CLEARED

May 28, 2010
85 days to decision

K100617 · Product code: **DQA** · Anesthesiology
Source: https://www.510kdatabase.net/k100617/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Oximeter (DQA)
Date received	Mar 4, 2010
Decision date	May 28, 2010
Days to decision	85 days
Third-party review	No
Summary / Statement	Summary
Other names	S2-20/20D

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...