

K033998 MASIMO SET RAD-5V PULSE OXIMETER, MODEL RAD-5VMar 19, 2004
86 days to decisionK033998 · Product code: **DQA** · Anesthesiology
Source: <https://www.510kdatabase.net/k033998/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Oximeter (DQA)
Date received	Dec 24, 2003
Decision date	Mar 19, 2004
Days to decision	86 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Masimo Corp.
Location	Irvine, CA, US
Contact	JAMES J CRONIN
Website	http://www.masimo.com/
510(k) history	28 submissions · 28 cleared · 1997-2004

Masimo Corp. is an American health technology 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 1997. The company's regulatory submissions have focused exclusively on Anesthesiology devices, including pulse oximetry sensors, adaptor cables, and monitoring modules. The latest clearance on record dates to 2004, reflecting the company's historical regulato...