

**K012992 MASIMO SET RADICAL PULSE OXIMETER WITH  
SATSHARE AND MASIMO SERIES OF SENSORS AND CABLES**Oct 3, 2001  
27 days to decisionK012992 · Product code: **DQA** · Anesthesiology  
Source: <https://www.510kdatabase.net/k012992/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Oximeter (DQA)
Date received	Sep 6, 2001
Decision date	Oct 3, 2001
Days to decision	27 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

---

Company	<b>Masimo Corp.</b>
Location	Irvine, CA, US
Contact	JAMES J CRONIN
Website	<a href="http://www.masimo.com/">http://www.masimo.com/</a>
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...