FDA 510(k) Premarket Notification

CLEARED

K013792 MODIFICATION TO MASIMO SET RADICAL PULSE OXIMETER WITH SATSHARE AND LNOP SERIES OF SENSORS AND CABLES

Dec 11, 2001
27 days to decision

K013792 · Product code: **DQA** · Anesthesiology
Source: https://www.510kdatabase.net/k013792/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Oximeter (DQA)
Date received	Nov 14, 2001
Decision date	Dec 11, 2001
Days to decision	27 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...