

**K990966 MASIMO SET 2000 PULSE OXIMETER, MASIMO LNOP
-ADT-ADULT/PEDIATRIC DISPOSABLE SENSOR, MASIMO
LNOP -PDT-PEDIATRIC/SMALL DIS**Jun 7, 1999
76 days to decisionK990966 · Product code: **DQA** · Anesthesiology
Source: <https://www.510kdatabase.net/k990966/>**SUBMISSION DETAILS**

| | |
|-----------------------|------------------------------------|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Oximeter (DQA) |
| Date received | Mar 23, 1999 |
| Decision date | Jun 7, 1999 |
| Days to decision | 76 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...