

K060143 LNCS AND SPO2.COM SENSORSJun 16, 2006
148 days to decisionK060143 · Product code: **DQA** · Anesthesiology
Source: <https://www.510kdatabase.net/k060143/>**SUBMISSION DETAILS**

| | |
|-----------------------|------------------------------------|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Oximeter (DQA) |
| Date received | Jan 19, 2006 |
| Decision date | Jun 16, 2006 |
| Days to decision | 148 days |
| Third-party review | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---|
| Company | Masimo Corporation |
| Location | Irvine, CA, US |
| Contact | JAMES J CRONIN |
| 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...
