

K113596 MASIMO SET REUSABLE OXIMETRY SENSORSFeb 24, 2012
81 days to decisionK113596 · Product code: **DQA** · Anesthesiology
Source: <https://www.510kdatabase.net/k113596/>**SUBMISSION DETAILS**

| | |
|-----------------------|------------------------------------|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Special |
| Device classification | Oximeter (DQA) |
| Date received | Dec 5, 2011 |
| Decision date | Feb 24, 2012 |
| Days to decision | 81 days |
| Third-party review | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---|
| Company | Masimo Corporation |
| Location | Irvine, CA, US |
| Contact | DAVID COLLETTE |
| 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...
