

**K063140 RAINBOW ADHESIVE CO-OXIMETRY SENSORS**Dec 29, 2006  
74 days to decisionK063140 · Product code: **DQA** · Anesthesiology  
Source: <https://www.510kdatabase.net/k063140/>**SUBMISSION DETAILS**

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|                       |                                    |
|-----------------------|------------------------------------|
| Decision              | Substantially Equivalent (Cleared) |
| Submission type       | Special                            |
| Device classification | Oximeter (DQA)                     |
| Date received         | Oct 16, 2006                       |
| Decision date         | Dec 29, 2006                       |
| Days to decision      | 74 days                            |
| Third-party review    | No                                 |
| Summary / Statement   | Summary                            |

**APPLICANT**

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

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