

K852624 OXY-TWOSep 18, 1985
90 days to decisionK852624 · Product code: **BYG** · AnesthesiologySource: <https://www.510kdatabase.net/k852624/>**SUBMISSION DETAILS**

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|-----------------------|------------------------------------|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Mask, Oxygen (BYG) |
| Date received | Jun 20, 1985 |
| Decision date | Sep 18, 1985 |
| Days to decision | 90 days |
| Third-party review | No |

APPLICANT

| | |
|----------------|---|
| Company | Ashai Co. , Ltd. |
| Location | Australia, AU |
| Contact | KALNIN |
| 510(k) history | 12 submissions · 12 cleared · 1985-1987 |

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k852624/>; Data sourced from FDA 510(k) public records (accessdata.fda.gov).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated May 27, 2026