

**K852626 AERO-MASK ONE**Sep 18, 1985  
90 days to decisionK852626 · Product code: **BYG** · AnesthesiologySource: <https://www.510kdatabase.net/k852626/>**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**

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

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k852626/>, Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://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](http://accessdata.fda.gov). - Generated May 27, 2026