

**K854458 CUSHION-FLEX TM-CPAP FACE MASK**Jan 15, 1986  
70 days to decisionK854458 · Product code: **BYE** · AnesthesiologySource: <https://www.510kdatabase.net/k854458/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Attachment, Breathing, Positive End Expiratory Pressure (BYE)
Date received	Nov 6, 1985
Decision date	Jan 15, 1986
Days to decision	70 days
Third-party review	No

**APPLICANT**

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Company	<b>Life Design Systems, Inc.</b>
Location	Mchenry, IL, US
Contact	GILBERT M KIRK
510(k) history	29 submissions · 29 cleared · 1982-1992

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k854458/>; 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