

**K861758 CUSHION-FLEX™ NASAL CPAP MASK FOR SLEEP APNEA**Jul 14, 1986  
69 days to decisionK861758 · Product code: **BYE** · Anesthesiology  
Source: <https://www.510kdatabase.net/k861758/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Attachment, Breathing, Positive End Expiratory Pressure (BYE)
Date received	May 6, 1986
Decision date	Jul 14, 1986
Days to decision	69 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/k861758/>; 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