

**K842054 COBE AEPS**Aug 2, 1984  
72 days to decisionK842054 · Product code: **KRL** · CardiovascularSource: <https://www.510kdatabase.net/k842054/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Detector, Bubble, Cardiopulmonary Bypass (KRL)
Date received	May 22, 1984
Decision date	Aug 2, 1984
Days to decision	72 days
Third-party review	No

**APPLICANT**

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Company	<b>Cobe Laboratories, Inc.</b>
Location	Mchenry, IL, US
Website	<a href="https://www.gambro.com">https://www.gambro.com</a>
510(k) history	77 submissions · 77 cleared · 1976-1993

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k842054/>; 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 26, 2026