

**K823338 COBE HEMOCONCENTRATOR 1.3**Jan 7, 1983  
60 days to decisionK823338 · Product code: **KDI** · Gastroenterology & UrologySource: <https://www.510kdatabase.net/k823338/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Dialyzer, High Permeability With Or Without Sealed Dialysate System (KDI)
Date received	Nov 8, 1982
Decision date	Jan 7, 1983
Days to decision	60 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/k823338/>; 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