

**K854309 GAMBRO BLOOD CONCENTRATOR SETS 16,60,200**Dec 13, 1985  
49 days to decisionK854309 · Product code: **KDI** · Gastroenterology & UrologySource: <https://www.510kdatabase.net/k854309/>**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	Oct 25, 1985
Decision date	Dec 13, 1985
Days to decision	49 days
Third-party review	No

**APPLICANT**

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Company	<b>Gambro, Inc.</b>
Location	Mchenry, IL, US
Contact	JEFFREY SHIDEMAN
510(k) history	86 submissions · 86 cleared · 1976-2009

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k854309/>; 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 23, 2026