

**K830284 FH 101, FH 202 & FH 303 FIBER HEMOFILTER**Mar 2, 1983  
34 days to decisionK830284 · Product code: **KDI** · Gastroenterology & UrologySource: <https://www.510kdatabase.net/k830284/>**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	Jan 27, 1983
Decision date	Mar 2, 1983
Days to decision	34 days
Third-party review	No

**APPLICANT**

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Company	<b>Gambro, Inc.</b>
Location	Mchenry, IL, US
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/k830284/> 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