

**K853510 MINIFILTER HEMOFILTER**Sep 12, 1985  
22 days to decisionK853510 · Product code: **KDI** · Gastroenterology & UrologySource: <https://www.510kdatabase.net/k853510/>**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	Aug 21, 1985
Decision date	Sep 12, 1985
Days to decision	22 days
Third-party review	No

**APPLICANT**

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Company	<b>Amicon, Inc.</b>
Location	Mchenry, IL, US
Contact	JAMES M DELANCY
510(k) history	20 submissions · 20 cleared · 1976-1993

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k853510/>, 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 14, 2026