

**K883195 FRESENIUS F8 DIALYZER**Sep 13, 1988  
47 days to decisionK883195 · Product code: **KDI** · Gastroenterology & UrologySource: <https://www.510kdatabase.net/k883195/>**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	Jul 28, 1988
Decision date	Sep 13, 1988
Days to decision	47 days
Third-party review	No

**APPLICANT**

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Company	<b>Fresenius USA, Inc.</b>
Location	Walker, MI, US
Contact	THOMAS E CANE
510(k) history	38 submissions · 37 cleared · 1984-1999

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k883195/>; 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 25, 2026