

**K113427 FRESENIUS 2008T HEMODIALYSIS MACHINE**Dec 21, 2011  
30 days to decisionK113427 · Product code: **KDI** · Gastroenterology & UrologySource: <https://www.510kdatabase.net/k113427/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Dialyzer, High Permeability With Or Without Sealed Dialysate System (KDI)
Date received	Nov 21, 2011
Decision date	Dec 21, 2011
Days to decision	30 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Fresenius Medical Care North America</b>
Location	Lexington, MA, US
Contact	DENISE OPPERMANN
510(k) history	43 submissions · 43 cleared · 1998-2025

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k113427/> 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