

**K123835 2008 HEMODIALYSIS SORBENT SYSTEM**Feb 15, 2013  
64 days to decisionK123835 · Product code: **FKT** · Gastroenterology & UrologySource: <https://www.510kdatabase.net/k123835/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	System, Dialysate Delivery, Sorbent Regenerated (FKT)
Date received	Dec 13, 2012
Decision date	Feb 15, 2013
Days to decision	64 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Renal Solutions, Inc.</b>
Location	Apollo, PA, US
Contact	DAVID VANELLA
510(k) history	9 submissions · 9 cleared · 2003-2013

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k123835/> 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 June 9, 2026