

K093362 2008 HEMODIALYSIS SORBENT SYSTEMAug 13, 2010
289 days to decisionK093362 · Product code: **FKT** · Gastroenterology & UrologySource: <https://www.510kdatabase.net/k093362/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Abbreviated
Device classification	System, Dialysate Delivery, Sorbent Regenerated (FKT)
Date received	Oct 28, 2009
Decision date	Aug 13, 2010
Days to decision	289 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

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