FDA 510(k) Premarket Notification

K123835 2008 HEMODIALYSIS SORBENT SYSTEM

CLEARED

Feb 15, 2013
64 days to decision

K123835 · Product code: **FKT** · Gastroenterology & Urology
Source: https://www.510kdatabase.net/k123835/

SUBMISSION DETAILS

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

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