

K121497 VENOFER PUMPAug 17, 2012
88 days to decisionK121497 · Product code: **KDI** · Gastroenterology & Urology
Source: <https://www.510kdatabase.net/k121497/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Dialyzer, High Permeability With Or Without Sealed Dialysate System (KDI)
Date received	May 21, 2012
Decision date	Aug 17, 2012
Days to decision	88 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

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