

**K103564 VENOFER PUMP**Feb 10, 2011  
66 days to decisionK103564 · Product code: **KDI** · Gastroenterology & Urology  
Source: <https://www.510kdatabase.net/k103564/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Dialyzer, High Permeability With Or Without Sealed Dialysate System (KDI)
Date received	Dec 6, 2010
Decision date	Feb 10, 2011
Days to decision	66 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

---

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

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k103564/> 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