FDA 510(k) Premarket Notification

K103564 VENOFER PUMP

CLEARED

Feb 10, 2011
66 days to decision

K103564 · 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	**Renal Solutions, Inc.**
Location	Apollo, PA, US
Contact	DAVID VANELLA
510(k) history	9 submissions · 9 cleared · 2003-2013