

K130039 REVACLEAR 300 DIALYZER, REVACLEAR 400 DIALYZERMay 2, 2013
115 days to decisionK130039 · Product code: **KDI** · Gastroenterology & Urology
Source: <https://www.510kdatabase.net/k130039/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Dialyzer, High Permeability With Or Without Sealed Dialysate System (KDI)
Date received	Jan 7, 2013
Decision date	May 2, 2013
Days to decision	115 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Gambro Renal Products, Inc.
Location	Lakewood, CO, US
Contact	KAE MILLER
510(k) history	13 submissions · 13 cleared · 2004-2014

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k130039/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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