FDA 510(k) Premarket Notification

K130039 REVACLEAR 300 DIALYZER, REVACLEAR 400 DIALYZER

CLEARED

May 2, 2013
115 days to decision

K130039 · 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