

K083158 EXALIS, SOFTWARE VERSION 1.15Jun 5, 2009
224 days to decisionK083158 · Product code: **KDI** · Gastroenterology & Urology
Source: <https://www.510kdatabase.net/k083158/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Dialyzer, High Permeability With Or Without Sealed Dialysate System (KDI)
Date received	Oct 24, 2008
Decision date	Jun 5, 2009
Days to decision	224 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Gambro, Inc.
Location	Mchenry, IL, US
Contact	KAE MILLER
510(k) history	86 submissions · 86 cleared · 1976-2009

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