

**K070643 PHOENIX HEMODIALYSIS DELIVERY SYSTEM,
VERSION 3.35**Nov 2, 2007
239 days to decisionK070643 · Product code: **KDI** · Gastroenterology & Urology
Source: <https://www.510kdatabase.net/k070643/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Dialyzer, High Permeability With Or Without Sealed Dialysate System (KDI)
Date received	Mar 8, 2007
Decision date	Nov 2, 2007
Days to decision	239 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

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