

**K933818 GAMBRO POLYFLUX II HEMODIALYZERIALYZER
HEMODIAFILTER**Jan 25, 1995
539 days to decisionK933818 · Product code: **KDI** · Gastroenterology & Urology
Source: <https://www.510kdatabase.net/k933818/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Dialyzer, High Permeability With Or Without Sealed Dialysate System (KDI)
Date received	Aug 4, 1993
Decision date	Jan 25, 1995
Days to decision	539 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	C.G.H. Medical, Inc.
Location	Lakewood, CO, US
Contact	JEFFREY R SHIDEMAN, PHD.
510(k) history	11 submissions · 11 cleared · 1991-1995

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