

**K982413 COBE ARYLANE H1, H4, H6 & H9
HEMODIALYZERS/FILTERS**Apr 21, 1999
282 days to decisionK982413 · Product code: **KDI** · Gastroenterology & Urology
Source: <https://www.510kdatabase.net/k982413/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Dialyzer, High Permeability With Or Without Sealed Dialysate System (KDI)
Date received	Jul 13, 1998
Decision date	Apr 21, 1999
Days to decision	282 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Gambro Healthcare
Location	Oklahoma City, OK, US
Contact	JEFFREY R SHIDEMAN
510(k) history	13 submissions · 13 cleared · 1996-2000

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