

**K952342 GAMBRO LUNDIA 94-700 & SIGMA 800
HEMODIALYZERS**Sep 15, 1995
119 days to decisionK952342 · Product code: **KDI** · Gastroenterology & Urology
Source: <https://www.510kdatabase.net/k952342/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Dialyzer, High Permeability With Or Without Sealed Dialysate System (KDI)
Date received	May 19, 1995
Decision date	Sep 15, 1995
Days to decision	119 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	Cobe Renal Care, Inc.
Location	Lakewood, CO, US
Contact	JEFFREY R SHIDEMAN
510(k) history	14 submissions · 14 cleared · 1994-1997

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k952342/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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