FDA 510(k) Premarket Notification

K952342 GAMBRO LUNDIA 94-700 & SIGMA 800 HEMODIALYZERS

CLEARED

Sep 15, 1995
119 days to decision

K952342 · 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