FDA 510(k) Premarket Notification

K823338 COBE HEMOCONCENTRATOR 1.3

CLEARED

Jan 7, 1983
60 days to decision

K823338 · Product code: **KDI** · Gastroenterology & Urology
Source: https://www.510kdatabase.net/k823338/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Dialyzer, High Permeability With Or Without Sealed Dialysate System (KDI)
Date received	Nov 8, 1982
Decision date	Jan 7, 1983
Days to decision	60 days
Third-party review	No

APPLICANT

Company	**Cobe Laboratories, Inc.**
Location	Mchenry, IL, US
Website	https://www.gambro.com
510(k) history	77 submissions · 77 cleared · 1976-1993