FDA 510(k) Premarket Notification

K801480 GAMBRO LUNDIA MAJOR HIGH FLUX HEMODIALYZ

CLEARED

Aug 27, 1980
64 days to decision

K801480 · Product code: **KDI** · Gastroenterology & Urology
Source: https://www.510kdatabase.net/k801480/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Dialyzer, High Permeability With Or Without Sealed Dialysate System (KDI)
Date received	Jun 24, 1980
Decision date	Aug 27, 1980
Days to decision	64 days
Third-party review	No

APPLICANT

Company	**Gambro, Inc.**
Location	Mchenry, IL, US
510(k) history	86 submissions · 86 cleared · 1976-2009