FDA 510(k) Premarket Notification

K830596 ULTRAFILTRATION MONITOR UFM-10-2

CLEARED

Apr 27, 1983
62 days to decision

K830596 · Product code: **KDI** · Gastroenterology & Urology
Source: https://www.510kdatabase.net/k830596/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Dialyzer, High Permeability With Or Without Sealed Dialysate System (KDI)
Date received	Feb 24, 1983
Decision date	Apr 27, 1983
Days to decision	62 days
Third-party review	No

APPLICANT

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