FDA 510(k) Premarket Notification

K802250 DIALYSIS CONTROL UNIT-CENTRY 2000

CLEARED

Dec 10, 1980
85 days to decision

K802250 · Product code: **FKP** · Gastroenterology & Urology
Source: https://www.510kdatabase.net/k802250/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Dialysate Delivery, Single Patient (FKP)
Date received	Sep 16, 1980
Decision date	Dec 10, 1980
Days to decision	85 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

510k Database - www.510kdatabase.net
Device record: https://www.510kdatabase.net/k802250/ Data sourced from FDA 510(k) public records (accessdata.fda.gov).
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