FDA 510(k) Premarket Notification

K881811 COBE CENTRYSYSTEM HOLLOW FIBER DIALYZERS

CLEARED

Sep 15, 1988
140 days to decision

K881811 · Product code: **FJI** · Gastroenterology & Urology
Source: https://www.510kdatabase.net/k881811/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Dialyzer, Capillary, Hollow Fiber (FJI)
Date received	Apr 28, 1988
Decision date	Sep 15, 1988
Days to decision	140 days
Third-party review	No

APPLICANT

Company	**Cobe Laboratories, Inc.**
Location	Mchenry, IL, US
Contact	MARY L ARMSTRONG
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/k881811/ Data sourced from FDA 510(k) public records (accessdata.fda.gov).
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