FDA 510(k) Premarket Notification

K880021 COBE CML3

CLEARED

Apr 1, 1988
87 days to decision

K880021 · Product code: **DTZ** · Cardiovascular
Source: https://www.510kdatabase.net/k880021/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Oxygenator, Cardiopulmonary Bypass (DTZ)
Date received	Jan 5, 1988
Decision date	Apr 1, 1988
Days to decision	87 days
Third-party review	No

APPLICANT

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