FDA 510(k) Premarket Notification

K812093 COBE HEAT EXCHANGER RESERVOIR MODULE

CLEARED

Aug 13, 1981
20 days to decision

K812093 · Product code: **DTR** · Cardiovascular
Source: https://www.510kdatabase.net/k812093/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Heat-exchanger, Cardiopulmonary Bypass (DTR)
Date received	Jul 24, 1981
Decision date	Aug 13, 1981
Days to decision	20 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/k812093/ Data sourced from FDA 510(k) public records (accessdata.fda.gov).
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