FDA 510(k) Premarket Notification

K781764 PAD, COOLING #27-999

CLEARED

Dec 4, 1978
49 days to decision

K781764 · Product code: **DTR** · Cardiovascular
Source: https://www.510kdatabase.net/k781764/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Heat-exchanger, Cardiopulmonary Bypass (DTR)
Date received	Oct 16, 1978
Decision date	Dec 4, 1978
Days to decision	49 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/k781764/ Data sourced from FDA 510(k) public records (accessdata.fda.gov).
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