FDA 510(k) Premarket Notification

K974812 COBE(R) CML DUO(R) WITH SMART(TM) SURFACE MODIFIED MEMBRANCE OXYGENATOR

CLEARED

Jun 1, 1998
160 days to decision

K974812 · Product code: **DTZ** · Cardiovascular
Source: https://www.510kdatabase.net/k974812/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Oxygenator, Cardiopulmonary Bypass (DTZ)
Date received	Dec 23, 1997
Decision date	Jun 1, 1998
Days to decision	160 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Cobe Cardiovascular, Inc.**
Location	Arvada, CO, US
Contact	LYNNE LEONARD
510(k) history	43 submissions · 43 cleared · 1992-2005