

**K974812 COBE(R) CML DUO(R) WITH SMART(TM) SURFACE
MODIFIED MEMBRANCE OXYGENATOR**Jun 1, 1998
160 days to decisionK974812 · 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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k974812/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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