

**K963518 COBE OPTIMA XP HOLLOW FIBER MEMBRANE
OXYGENATOR**Dec 8, 1997
461 days to decisionK963518 · Product code: **DTZ** · Cardiovascular
Source: <https://www.510kdatabase.net/k963518/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Oxygenator, Cardiopulmonary Bypass (DTZ)
Date received	Sep 3, 1996
Decision date	Dec 8, 1997
Days to decision	461 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Cobe Cardiovascular, Inc.
Location	Arvada, CO, US
Contact	MARY L ARMSTRONG
510(k) history	43 submissions · 43 cleared · 1992-2005

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k963518/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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