

**K000255 COBE SMARXT OPTIMA XP SURFACE MODIFIED
HOLLOW FIBER MEMBRANE OXYGENATOR**Apr 25, 2000
88 days to decisionK000255 · Product code: DTZ · Cardiovascular
Source: <https://www.510kdatabase.net/k000255/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Oxygenator, Cardiopulmonary Bypass (DTZ)
Date received	Jan 28, 2000
Decision date	Apr 25, 2000
Days to decision	88 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/k000255/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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