

**K013480 COBE SMARXT OPTIMIN SURFACE MODIFIED
HOLLOW FIBER MEMBRANE OXYGENATOR**

Nov 16, 2001
28 days to decision

K013480 · Product code: DTZ · Cardiovascular
Source: <https://www.510kdatabase.net/k013480/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Oxygenator, Cardiopulmonary Bypass (DTZ)
Date received	Oct 19, 2001
Decision date	Nov 16, 2001
Days to decision	28 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

510k Database - www.510kdatabase.net

Device record: <https://www.510kdatabase.net/k013480/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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