

**K004046 COBE VVR 4000 FILTERED HARDSHELL VENOUS RESERVOIR, COBE SMARXT VVR 4000 FILTERED HARDSHELL VENOUS RESERVOIR**Apr 26, 2001  
118 days to decisionK004046 · Product code: **DTP** · Cardiovascular  
Source: <https://www.510kdatabase.net/k004046/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Defoamer, Cardiopulmonary Bypass (DTP)
Date received	Dec 29, 2000
Decision date	Apr 26, 2001
Days to decision	118 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k004046/>; Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://accessdata.fda.gov)).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at [accessdata.fda.gov](http://accessdata.fda.gov). - Generated May 25, 2026