

**K994389 COBE HVR 2200 HARDSHELL VENOUS RESERVOIR,  
FILTERED**Mar 27, 2000  
90 days to decisionK994389 · Product code: **DTN** · Cardiovascular  
Source: <https://www.510kdatabase.net/k994389/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Reservoir, Blood, Cardiopulmonary Bypass (DTN)
Date received	Dec 28, 1999
Decision date	Mar 27, 2000
Days to decision	90 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/k994389/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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