

K984456 COBE HVR 4000 FILTERED HARDSHELL VENOUS RESERVOIRJan 11, 1999
27 days to decisionK984456 · Product code: **DTN** · Cardiovascular
Source: <https://www.510kdatabase.net/k984456/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Reservoir, Blood, Cardiopulmonary Bypass (DTN)
Date received	Dec 15, 1998
Decision date	Jan 11, 1999
Days to decision	27 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/k984456/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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