

**K971669 COBE HVR 4000 FILTERED AND NONFILTERED  
HARDSHELL VENOUS RESERVOIR**Jul 23, 1997  
78 days to decisionK971669 · Product code: DTN · Cardiovascular  
Source: <https://www.510kdatabase.net/k971669/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Reservoir, Blood, Cardiopulmonary Bypass (DTN)
Date received	May 6, 1997
Decision date	Jul 23, 1997
Days to decision	78 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Cobe Cardiovascular, Inc.</b>
Location	Arvada, CO, US
Contact	MARY L ARMSTRONG
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/k971669/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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