

**K012898 MODIFICATION TO: CSC14 BLOOD CARDIOPLEGIA SYSTEM**Sep 17, 2001  
19 days to decisionK012898 · Product code: **DTR** · Cardiovascular  
Source: <https://www.510kdatabase.net/k012898/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Heat-exchanger, Cardiopulmonary Bypass (DTR)
Date received	Aug 29, 2001
Decision date	Sep 17, 2001
Days to decision	19 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/k012898/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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