

**K944267 HEAT EXCHANGER MODIFICATION FOR DUO AND OPTIMA**Apr 28, 1995  
239 days to decisionK944267 · Product code: **DTR** · Cardiovascular  
Source: <https://www.510kdatabase.net/k944267/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Heat-exchanger, Cardiopulmonary Bypass (DTR)
Date received	Sep 1, 1994
Decision date	Apr 28, 1995
Days to decision	239 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/k944267/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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