

**K964571 VISION CARDIOPLEGIA DELIVERY SYSTEM**Aug 8, 1997  
267 days to decisionK964571 · Product code: **DTR** · CardiovascularSource: <https://www.510kdatabase.net/k964571/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Heat-exchanger, Cardiopulmonary Bypass (DTR)
Date received	Nov 14, 1996
Decision date	Aug 8, 1997
Days to decision	267 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Lifestream Int&amp;apos;L, Inc.</b>
Location	Sugar Land, TX, US
Contact	ROSINA ROBINSON, R.N., RAC
510(k) history	23 submissions · 23 cleared · 1984-1997

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k964571/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://accessdata.fda.gov)).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at [accessdata.fda.gov](http://accessdata.fda.gov). - Generated May 22, 2026