

**K113667 CARDIOPLEGIA DELIVERY SETS CARDIOPLEGIA  
DELIVERY SETS WITH DURAFLO COATING**Jan 12, 2012  
30 days to decisionK113667 · Product code: DTL · Cardiovascular  
Source: <https://www.510kdatabase.net/k113667/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Adaptor, Stopcock, Manifold, Fitting, Cardiopulmonary Bypass (DTL)
Date received	Dec 13, 2011
Decision date	Jan 12, 2012
Days to decision	30 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Edwards Lifesciences, LLC</b>
Location	Irvine, CA, US
Contact	KAREN JONES
Website	<a href="https://www.edwards.com">https://www.edwards.com</a>
510(k) history	135 submissions · 129 cleared · 1979-2026

Edwards Lifesciences, LLC is a global structural heart innovation company headquartered in Irvine, California. The company specializes in advanced medical devices for cardiovascular disease management. Edwards Lifesciences has established a strong FDA 510(k) regulatory track record with FDA 510(k) cleared devices from total submissions since 1979. The company's portfolio is dominated by Cardiovascular devices, which represent 88% of all submissions. The latest clearance was received in 2026, demonstrating continued active development and regulatory engagement. Recent clea...

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)

Device record: <https://www.510kdatabase.net/k113667/>. Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://accessdata.fda.gov)).

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