

**K113411 EDWARD VENT CATHETERS EDWARD VENT  
CATHETERS WITH DURAFLO COATING DISPERSION AORTIC  
PERFUSION CANNULA**Jun 11, 2012  
206 days to decisionK113411 · Product code: **DWF** · Cardiovascular  
Source: <https://www.510kdatabase.net/k113411/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter, Cannula And Tubing, Vascular, Cardiopulmonary Bypass (DWF)
Date received	Nov 18, 2011
Decision date	Jun 11, 2012
Days to decision	206 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Edwards Lifesciences, LLC</b>
Location	Irvine, CA, US
Contact	DANNETTE CROOMS
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...