

**K113459 ANTEPLEGIA CATHETER ANTEGRADE
CARDIOPLEGIA CATHETER AORTIC ROOT CANNULA
ANTEGRADE CATHETER WITH DURAFLO COATING**Jun 29, 2012
220 days to decisionK113459 · Product code: **DWF** · Cardiovascular
Source: <https://www.510kdatabase.net/k113459/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter, Cannula And Tubing, Vascular, Cardiopulmonary Bypass (DWF)
Date received	Nov 22, 2011
Decision date	Jun 29, 2012
Days to decision	220 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Edwards Lifesciences, LLC
Location	Irvine, CA, US
Contact	DANNETTE CROOMS
Website	https://www.edwards.com
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...