

**K113565 MULTI-MED CENTRAL VENOUS CATHETERS (CVCS),
WITH AND WITHOUT HEPARIN VANTEX CENTRAL VENOUS
CATHETERS (CVCS), WITH HEPARIN**May 18, 2012
168 days to decisionK113565 · Product code: **FOZ** · General Hospital
Source: <https://www.510kdatabase.net/k113565/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Catheter, Intravascular, Therapeutic, Short-term Less Than 30 Days (FOZ)
Date received	Dec 2, 2011
Decision date	May 18, 2012
Days to decision	168 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Edwards Lifesciences, LLC
Location	Irvine, CA, US
Contact	MARGUEITE THOMLINSON
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...