

**K121185 EDWARDS PERCUTANEOUS SHEATH INTRODUCER**Aug 22, 2012  
126 days to decisionK121185 · Product code: **DYB** · Cardiovascular  
Source: <https://www.510kdatabase.net/k121185/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Introducer, Catheter (DYB)
Date received	Apr 18, 2012
Decision date	Aug 22, 2012
Days to decision	126 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Edwards Lifesciences, LLC</b>
Location	Irvine, CA, US
Contact	SPENCER WALKER
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...