FDA 510(k) Premarket Notification

CLEARED

K152225 Edwards eSheath Introducer Set

Nov 24, 2015
109 days to decision

K152225 · Product code: **DYB** · Cardiovascular
Source: https://www.510kdatabase.net/k152225/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Introducer, Catheter (DYB)
Date received	Aug 7, 2015
Decision date	Nov 24, 2015
Days to decision	109 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Edwards Lifesciences**
Location	Irvine, CA, US
Contact	KAREN REYNOLDS
Website	http://www.edwards.com
510(k) history	20 submissions · 19 cleared · 2011-2026

Edwards Lifesciences is the leading global structural heart innovation company dedicated to improving patient lives through breakthrough cardiovascular technologies. The company partners with physicians to develop products for patients fighting heart disease, with a manufacturing facility in Irvine, US. Edwards Lifesciences has received FDA 510(k) clearances from total submissions since 2011. The company specializes in Cardiovascular devices, which represent the dominant focus of its regulatory portfolio. The latest clearance in 2025 reflects continued innovation and acti...