FDA 510(k) Premarket Notification

CLEARED

K254279 Edwards eSheath+ introducer set

Apr 17, 2026
108 days to decision

K254279 · Product code: **DYB** · Cardiovascular
Source: https://www.510kdatabase.net/k254279/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Introducer, Catheter (DYB)
Date received	Dec 30, 2025
Decision date	Apr 17, 2026
Days to decision	108 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Edwards Lifesciences**
Location	Irvine, CA, US
Contact	Venkatesh Rane
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...