

K252364 Edwards eSheath Optima introducer setAug 29, 2025
31 days to decisionK252364 · Product code: **DYB** · CardiovascularSource: <https://www.510kdatabase.net/k252364/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Introducer, Catheter (DYB)
Date received	Jul 29, 2025
Decision date	Aug 29, 2025
Days to decision	31 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...