

**K162184 Edwards eSheath Introducer Set**Sep 2, 2016  
29 days to decisionK162184 · Product code: **DYB** · CardiovascularSource: <https://www.510kdatabase.net/k162184/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Introducer, Catheter (DYB)
Date received	Aug 4, 2016
Decision date	Sep 2, 2016
Days to decision	29 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

---

Company	<b>Edward Lifesciences</b>
Location	Irvine, CA, US
Contact	Yi Gao
510(k) history	1 submissions · 1 cleared · 2016-2016

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k162184/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://accessdata.fda.gov)).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at [accessdata.fda.gov](http://accessdata.fda.gov). - Generated June 2, 2026