

**K032900 LIFESPAN REINFORCED EPTFE STRAIGHT
VASCULAR GRAFTS, EXTERNALLY SUPPORTED VASCULAR
GRAFTS, STEPPED VASCULAR GRAFTS**Dec 4, 2003
78 days to decisionK032900 · Product code: **DSY** · Cardiovascular
Source: <https://www.510kdatabase.net/k032900/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Prosthesis, Vascular Graft, Of 6mm And Greater Diameter (DSY)
Date received	Sep 17, 2003
Decision date	Dec 4, 2003
Days to decision	78 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Edwards Lifesciences, LLC
Location	Irvine, CA, US
Contact	Daun Putnam
Website	https://www.edwards.com
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...