FDA 510(k) Premarket Notification

CLEARED

K001565 STEERABLE RETROGRADE CARDIOPLEGIA CANNULA WITH AND WITHOUT DURAFLO TREATMENT, MODELS SRCO14MIB, DIISRCO14MIB

Aug 10, 2000
83 days to decision

K001565 · Product code: **DWF** · Cardiovascular
Source: https://www.510kdatabase.net/k001565/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter, Cannula And Tubing, Vascular, Cardiopulmonary Bypass (DWF)
Date received	May 19, 2000
Decision date	Aug 10, 2000
Days to decision	83 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Edwards Lifesciences, LLC**
Location	Irvine, CA, US
Contact	JOHN W SMITH
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...