FDA 510(k) Premarket Notification

CLEARED

K233895 EZ Glide Aortic Perfusion Cannulae (EZC21A, EZC21TA, EZC24A, EZC24TA, EZF21A, EZF21TA, EZF24A, EZF24TA, EZS21A, EZS21TA, EZS24A and EZS24TA)

Feb 5, 2024
56 days to decision

K233895 · Product code: **DWF** · Cardiovascular
Source: https://www.510kdatabase.net/k233895/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Catheter, Cannula And Tubing, Vascular, Cardiopulmonary Bypass (DWF)
Date received	Dec 11, 2023
Decision date	Feb 5, 2024
Days to decision	56 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary
Other names	OptiSite Arterial Perfusion Cannulae (OPTI16, OPTI18, OPTI20 and OPTI22); EndoReturn Arterial Cannulae (ER21B and ER23B);

APPLICANT

Company	**Edwards Lifesciences**
Location	Irvine, CA, US
Contact	Peter Lindwall
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...