FDA 510(k) Premarket Notification

CLEARED

K241330 Fogarty Fortis Arterial Embolectomy Catheter

Jul 2, 2024
53 days to decision

K241330 · Product code: **DXE** · Cardiovascular
Source: https://www.510kdatabase.net/k241330/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter, Embolectomy (DXE)
Date received	May 10, 2024
Decision date	Jul 2, 2024
Days to decision	53 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Edwards Lifesciences**
Location	Irvine, CA, US
Contact	Aeree Lee
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...