FDA 510(k) Premarket Notification

K233820 Fogarty Arterial Embolectomy Catheter with Gate Valve

CLEARED

May 22, 2024
173 days to decision

K233820 · Product code: **DXE** · Cardiovascular
Source: https://www.510kdatabase.net/k233820/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter, Embolectomy (DXE)
Date received	Dec 1, 2023
Decision date	May 22, 2024
Days to decision	173 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Edwards Lifesciences**
Location	Irvine, CA, US
Contact	Yagna Angirish
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...