FDA 510(k) Premarket Notification

CLEARED

K240078 Fogarty Thru-Lumen Embolectomy Catheter

Aug 28, 2024
230 days to decision

K240078 · Product code: **DXE** · Cardiovascular
Source: https://www.510kdatabase.net/k240078/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter, Embolectomy (DXE)
Date received	Jan 11, 2024
Decision date	Aug 28, 2024
Days to decision	230 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Edwards Lifesciences, LLC**
Location	Irvine, CA, US
Contact	Carmen Chen
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...