

K233619 Fogarty Corkscrew CathetersMay 20, 2024
189 days to decisionK233619 · Product code: **DXE** · Cardiovascular
Source: <https://www.510kdatabase.net/k233619/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter, Embolectomy (DXE)
Date received	Nov 13, 2023
Decision date	May 20, 2024
Days to decision	189 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary
Other names	Fogarty Graft Thrombectomy Catheters

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...

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