

K193379 Fogarty Arterial Embolectomy Catheter, Fogarty Biliary Balloon ProbeJun 12, 2020
190 days to decisionK193379 · Product code: **DXE** · Cardiovascular
Source: <https://www.510kdatabase.net/k193379/>**SUBMISSION DETAILS**

| | |
|-----------------------|------------------------------------|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Catheter, Embolectomy (DXE) |
| Date received | Dec 5, 2019 |
| Decision date | Jun 12, 2020 |
| Days to decision | 190 days |
| Third-party review | No |
| Combination product | No |
| PCCP authorized | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---|
| Company | Edwards Lifesciences, LLC |
| Location | Irvine, CA, US |
| Contact | Wendy Vera Gonzalez |
| 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...