

**K173068 Performer Introducer**Nov 17, 2017  
49 days to decisionK173068 · Product code: **DYB** · Cardiovascular  
Source: <https://www.510kdatabase.net/k173068/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Introducer, Catheter (DYB)
Date received	Sep 29, 2017
Decision date	Nov 17, 2017
Days to decision	49 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

---

Company	<b>Cook Incorporated</b>
Location	Bloomington, IN, US
Contact	Reuben G. Lidster
510(k) history	175 submissions · 153 cleared · 2006-2024

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k173068/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://accessdata.fda.gov)).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at [accessdata.fda.gov](http://accessdata.fda.gov). - Generated May 31, 2026