

**K192769 Impella CP Introducer**Nov 18, 2019  
49 days to decisionK192769 · Product code: **DYB** · Cardiovascular  
Source: <https://www.510kdatabase.net/k192769/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Introducer, Catheter (DYB)
Date received	Sep 30, 2019
Decision date	Nov 18, 2019
Days to decision	49 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

---

Company	<b>Abiomed, Inc.</b>
Location	Danvers, MA, US
Contact	Robert Stewart
Website	<a href="http://www.abiomed.com/">http://www.abiomed.com/</a>
510(k) history	19 submissions · 17 cleared · 1989-2025

Abiomed, Inc. develops innovative cardiovascular devices focused on native heart recovery. Founded in 1981, the company specializes in percutaneous heart pump technology and related support systems. Now part of Johnson & Johnson, Abiomed operates with a manufacturing facility in Danvers, Massachusetts. Abiomed has received FDA 510(k) clearances from total submissions since 1989. Cardiovascular devices represent 84% of the company's regulatory portfolio. The company remains active, with the latest clearance in 2025, demonstrating continued innovation and market presence. T...

---