

K112892 IMPELLA 2.5 PLUS CATHETERSep 6, 2012
342 days to decisionK112892 · Product code: **PBL** · Cardiovascular
Source: <https://www.510kdatabase.net/k112892/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent - U
Submission type	Special
Date received	Sep 30, 2011
Decision date	Sep 6, 2012
Days to decision	342 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Abiomed, Inc.
Location	Danvers, MA, US
Contact	CAROLYN PEKAR
Website	http://www.abiomed.com/
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...

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