

K110845 IMPELLA CONTROLLER WITH FLOW CONTROLApr 27, 2011
30 days to decisionK110845 · Product code: **KFM** · Cardiovascular
Source: <https://www.510kdatabase.net/k110845/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Pump, Blood, Cardiopulmonary Bypass, Non-roller Type (KFM)
Date received	Mar 28, 2011
Decision date	Apr 27, 2011
Days to decision	30 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Abiomed, Inc.
Location	Danvers, MA, US
Contact	ROBERT STEWART
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...
