FDA 510(k) Premarket Notification

K093801 IMPELLA CONTROLLER

CLEARED

Jul 8, 2010
210 days to decision

K093801 · Product code: **KFM** · Cardiovascular
Source: https://www.510kdatabase.net/k093801/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Pump, Blood, Cardiopulmonary Bypass, Non-roller Type (KFM)
Date received	Dec 10, 2009
Decision date	Jul 8, 2010
Days to decision	210 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...