FDA 510(k) Premarket Notification

K202330 Impella XR Sheath Set

CLEARED

Dec 7, 2020
112 days to decision

K202330 · Product code: **DYB** · Cardiovascular
Source: https://www.510kdatabase.net/k202330/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Introducer, Catheter (DYB)
Date received	Aug 17, 2020
Decision date	Dec 7, 2020
Days to decision	112 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Abiomed, Inc.**
Location	Danvers, MA, US
Contact	J. Kenneth Ryder
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...

510k Database - www.510kdatabase.net
Device record: https://www.510kdatabase.net/k202330/ Data sourced from FDA 510(k) public records (accessdata.fda.gov).
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