FDA 510(k) Premarket Notification

K201116 Abiomed 23 Fr Sheath

CLEARED

Jun 15, 2020
49 days to decision

K201116 · Product code: **DYB** · Cardiovascular
Source: https://www.510kdatabase.net/k201116/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Introducer, Catheter (DYB)
Date received	Apr 27, 2020
Decision date	Jun 15, 2020
Days to decision	49 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Abiomed, Inc.**
Location	Danvers, MA, US
Contact	Sandy Fowler
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...