

K252766 14Fr Low Profile Introducer KitOct 8, 2025
40 days to decisionK252766 · Product code: **DYB** · Cardiovascular
Source: <https://www.510kdatabase.net/k252766/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Introducer, Catheter (DYB)
Date received	Aug 29, 2025
Decision date	Oct 8, 2025
Days to decision	40 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Abiomed, Inc.
Location	Danvers, MA, US
Contact	Anshul Shah
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...