

K171557 AcQRef Introducer SheathFeb 6, 2018
252 days to decisionK171557 · Product code: **DYB** · CardiovascularSource: <https://www.510kdatabase.net/k171557/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Introducer, Catheter (DYB)
Date received	May 30, 2017
Decision date	Feb 6, 2018
Days to decision	252 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Acutus Medical, Inc.
Location	Carlsbad, CA, US
Contact	Brenda Clay
510(k) history	24 submissions · 24 cleared · 2017-2023

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k171557/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated May 31, 2026