

K171081 Guider Catheter IntroducerMay 9, 2017
28 days to decisionK171081 · Product code: **DYB** · CardiovascularSource: <https://www.510kdatabase.net/k171081/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Introducer, Catheter (DYB)
Date received	Apr 11, 2017
Decision date	May 9, 2017
Days to decision	28 days
Third-party review	Yes
Summary / Statement	Summary

APPLICANT

Company	Rhythm Xience, Inc. (Rxi)
Location	Eden Prairie, MN, US
Contact	James Hassett
510(k) history	2 submissions · 2 cleared · 2017-2017

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k171081/> 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 June 1, 2026