

K170373 Flextra Steerable IntroducerFeb 27, 2017
20 days to decisionK170373 · Product code: **DYB** · CardiovascularSource: <https://www.510kdatabase.net/k170373/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Introducer, Catheter (DYB)
Date received	Feb 7, 2017
Decision date	Feb 27, 2017
Days to decision	20 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

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