

K181817 transGlideXT Expandable IntroducerMar 26, 2019
260 days to decisionK181817 · Product code: **DYB** · CardiovascularSource: <https://www.510kdatabase.net/k181817/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Introducer, Catheter (DYB)
Date received	Jul 9, 2018
Decision date	Mar 26, 2019
Days to decision	260 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Transaortic Medical, Inc.
Location	Morgan Hill, CA, US
Contact	Richard Ginn
510(k) history	2 submissions · 2 cleared · 2016-2019

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