

K152194 transGlide Expandable IntroducerApr 7, 2016
246 days to decisionK152194 · Product code: **DYB** · Cardiovascular
Source: <https://www.510kdatabase.net/k152194/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Introducer, Catheter (DYB)
Date received	Aug 5, 2015
Decision date	Apr 7, 2016
Days to decision	246 days
Third-party review	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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