

K102948 TORFLEX TRANSSEPTAL GUIDING SHEATHApr 1, 2011
178 days to decisionK102948 · Product code: **DYB** · CardiovascularSource: <https://www.510kdatabase.net/k102948/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Introducer, Catheter (DYB)
Date received	Oct 5, 2010
Decision date	Apr 1, 2011
Days to decision	178 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Baylis Medical Co., Inc.
Location	Mississauga, CA
Contact	MEGHAL KHAKHAR
510(k) history	28 submissions · 28 cleared · 1998-2013

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