

K183655 VersaCross Transseptal SheathMay 20, 2019
144 days to decisionK183655 · Product code: **DYB** · Cardiovascular
Source: <https://www.510kdatabase.net/k183655/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Introducer, Catheter (DYB)
Date received	Dec 27, 2018
Decision date	May 20, 2019
Days to decision	144 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Baylis Medical Company, Inc.
Location	Mississauga, Ontario, CA
Contact	Meghal Khakhar
510(k) history	24 submissions · 24 cleared · 2012-2025

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