

K190688 VersaCross Steerable Sheath, VersaCross Transseptal DilatorApr 17, 2019
30 days to decisionK190688 · Product code: **DYB** · Cardiovascular
Source: <https://www.510kdatabase.net/k190688/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Introducer, Catheter (DYB)
Date received	Mar 18, 2019
Decision date	Apr 17, 2019
Days to decision	30 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

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

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