

K191546 Epicardial Access SystemAug 2, 2019
51 days to decisionK191546 · Product code: **DYB** · Cardiovascular
Source: <https://www.510kdatabase.net/k191546/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Introducer, Catheter (DYB)
Date received	Jun 12, 2019
Decision date	Aug 2, 2019
Days to decision	51 days
Third-party review	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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k191546/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated May 14, 2026