

**K213582 Epicardial Access System**Jun 30, 2022  
230 days to decisionK213582 · Product code: **DYB** · CardiovascularSource: <https://www.510kdatabase.net/k213582/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Introducer, Catheter (DYB)
Date received	Nov 12, 2021
Decision date	Jun 30, 2022
Days to decision	230 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k213582/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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