

K243954 PeriCross™ Epicardial Access KitApr 24, 2025
122 days to decisionK243954 · Product code: **DYB** · CardiovascularSource: <https://www.510kdatabase.net/k243954/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Introducer, Catheter (DYB)
Date received	Dec 23, 2024
Decision date	Apr 24, 2025
Days to decision	122 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Circa Scientific, Inc.
Location	Englewood, CO, US
Contact	Alice Ouyang
510(k) history	6 submissions · 6 cleared · 2023-2025

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