

K243928 ViaOne Epicardial Access SystemMar 20, 2025
90 days to decisionK243928 · Product code: **DYB** · CardiovascularSource: <https://www.510kdatabase.net/k243928/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Introducer, Catheter (DYB)
Date received	Dec 20, 2024
Decision date	Mar 20, 2025
Days to decision	90 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Cardiovia , Ltd.
Location	Nazareth, IL
Contact	Orly Maor
510(k) history	1 submissions · 1 cleared · 2025-2025

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k243928/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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