FDA 510(k) Premarket Notification

K243928 ViaOne Epicardial Access System

CLEARED

Mar 20, 2025
90 days to decision

K243928 · Product code: **DYB** · Cardiovascular
Source: 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