

K250529 Globe Introducer (601-01001)Jun 3, 2025
99 days to decisionK250529 · Product code: **DRA** · Cardiovascular
Source: <https://www.510kdatabase.net/k250529/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter, Steerable (DRA)
Date received	Feb 24, 2025
Decision date	Jun 3, 2025
Days to decision	99 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Kardium, Inc.
Location	Burnaby, CA
Contact	Ricardo Romero
510(k) history	2 submissions · 2 cleared · 2025-2025

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k250529/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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