FDA 510(k) Premarket Notification

K250529 Globe Introducer (601-01001)

CLEARED

Jun 3, 2025
99 days to decision

K250529 · 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