

K252441 Primero Safe Access SystemSep 29, 2025
56 days to decisionK252441 · Product code: **DYB** · Cardiovascular
Source: <https://www.510kdatabase.net/k252441/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Introducer, Catheter (DYB)
Date received	Aug 4, 2025
Decision date	Sep 29, 2025
Days to decision	56 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	South53, LLC
Location	San Juan Capistrano, CA, US
Contact	Rodney Brenneman
510(k) history	1 submissions · 1 cleared · 2025-2025

REGULATORY CONSULTANT

Consulting firm	Biologics and Medical Device Consulting Group (Biomdg)
Contact	Octavio Cruz-Uribe

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: [FDA accessdata.fda.gov](https://accessdata.fda.gov)510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k252441/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated May 13, 2026