FDA 510(k) Premarket Notification

K252441 Primero Safe Access System

CLEARED

Sep 29, 2025
56 days to decision

K252441 · 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