

K251325 VersaCross Connect™ Transseptal DilatorMay 29, 2025
30 days to decisionK251325 · Product code: **DRE** · CardiovascularSource: <https://www.510kdatabase.net/k251325/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Dilator, Vessel, For Percutaneous Catheterization (DRE)
Date received	Apr 29, 2025
Decision date	May 29, 2025
Days to decision	30 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Baylis Medical Company, Inc.
Location	Mississauga, Ontario, CA
Contact	Ezgi Tas
510(k) history	24 submissions · 24 cleared · 2012-2025

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k251325/> 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