

K241720 VersaCross Connect™ Transseptal DilatorJul 12, 2024
28 days to decisionK241720 · Product code: **DRE** · CardiovascularSource: <https://www.510kdatabase.net/k241720/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Dilator, Vessel, For Percutaneous Catheterization (DRE)
Date received	Jun 14, 2024
Decision date	Jul 12, 2024
Days to decision	28 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/k241720/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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