FDA 510(k) Premarket Notification

K251325 VersaCross Connect™ Transseptal Dilator

CLEARED

May 29, 2025
30 days to decision

K251325 · Product code: **DRE** · Cardiovascular
Source: 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