

K242076 VersaCross™ RF WireNov 1, 2024
108 days to decisionK242076 · Product code: **DXF** · Cardiovascular
Source: <https://www.510kdatabase.net/k242076/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Catheter, Septostomy (DXF)
Date received	Jul 16, 2024
Decision date	Nov 1, 2024
Days to decision	108 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Baylis Medical Company
Location	Mississauga, CA
Contact	Neethi Murali
510(k) history	1 submissions · 1 cleared · 2024-2024

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k242076/> 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