FDA 510(k) Premarket Notification

K242076 VersaCross™ RF Wire

CLEARED

Nov 1, 2024
108 days to decision

K242076 · 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