FDA 510(k) Premarket Notification

K232562 PowerWire Radiofrequency Guidewire Kit

CLEARED

Feb 28, 2024
188 days to decision

K232562 · Product code: **PDU** · Cardiovascular
Source: https://www.510kdatabase.net/k232562/

SUBMISSION DETAILS

Decision	Substantially Equivalent - K
Submission type	Traditional
Device classification	Catheter For Crossing Total Occlusions (PDU)
Date received	Aug 24, 2023
Decision date	Feb 28, 2024
Days to decision	188 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Baylis Medical Technologies, Inc.**
Location	Mississauga, CA
Contact	Stephanie Gallone
510(k) history	5 submissions · 3 cleared · 2023-2026