FDA 510(k) Premarket Notification

K221351 Mechanical Guidewire

CLEARED

Dec 19, 2022
223 days to decision

K221351 · Product code: **DQX** · Cardiovascular
Source: https://www.510kdatabase.net/k221351/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Wire, Guide, Catheter (DQX)
Date received	May 10, 2022
Decision date	Dec 19, 2022
Days to decision	223 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	May Tsai
510(k) history	24 submissions · 24 cleared · 2012-2025