

K221390 BNLE Access GuidewireApr 28, 2023
350 days to decisionK221390 · Product code: **DQX** · Cardiovascular
Source: <https://www.510kdatabase.net/k221390/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Wire, Guide, Catheter (DQX)
Date received	May 13, 2022
Decision date	Apr 28, 2023
Days to decision	350 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Biomerics Nle
Location	Brooklyn Park, MN, US
Contact	Jason Albers
510(k) history	2 submissions · 2 cleared · 2023-2024

REGULATORY CONSULTANT

Consulting firm	Medventure Health
Contact	Jonathan Holmes

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: [FDA accessdata.fda.gov](https://accessdata.fda.gov)

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