

K232662 BNLE Hydrophilic Jacketed Peripheral GuidewireMay 14, 2024
257 days to decisionK232662 · Product code: **DQX** · CardiovascularSource: <https://www.510kdatabase.net/k232662/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Wire, Guide, Catheter (DQX)
Date received	Aug 31, 2023
Decision date	May 14, 2024
Days to decision	257 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

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