

K221279 pNOVUS 21 MicrocatheterNov 28, 2022
209 days to decisionK221279 · Product code: **DQO** · Neurology
Source: <https://www.510kdatabase.net/k221279/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter, Intravascular, Diagnostic (DQO)
Date received	May 3, 2022
Decision date	Nov 28, 2022
Days to decision	209 days
Third-party review	Yes
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Phenox, Ltd.
Location	Galway, IE
Contact	Sarah Cregg
510(k) history	3 submissions · 3 cleared · 2022-2026

REGULATORY CONSULTANT

Consulting firm	Regulatory Technology Services, LLC
Contact	Prithul Bom

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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