

K234115 APRO 55 CatheterMar 15, 2024
79 days to decisionK234115 · Product code: **DQY** · Neurology
Source: <https://www.510kdatabase.net/k234115/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter, Percutaneous (DQY)
Date received	Dec 27, 2023
Decision date	Mar 15, 2024
Days to decision	79 days
Third-party review	Yes
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Alembic, LLC
Location	Mountain View, CA, US
Contact	Lisa Yen
510(k) history	10 submissions · 10 cleared · 2023-2025

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

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