FDA 510(k) Premarket Notification

K234115 APRO 55 Catheter

CLEARED

Mar 15, 2024
79 days to decision

K234115 · 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