FDA 510(k) Premarket Notification

K250962 APRO 55 Intermediate Catheter

CLEARED

Apr 29, 2025
29 days to decision

K250962 · Product code: **DQY** · Neurology
Source: https://www.510kdatabase.net/k250962/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Catheter, Percutaneous (DQY)
Date received	Mar 31, 2025
Decision date	Apr 29, 2025
Days to decision	29 days
Third-party review	No
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