FDA 510(k) Premarket Notification

K231539 pRESET LITE Thrombectomy Device

CLEARED

Oct 21, 2023
144 days to decision

K231539 · Product code: **POL** · Neurology
Source: https://www.510kdatabase.net/k231539/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Neurovascular Mechanical Thrombectomy Device For Acute Ischemic Stroke Treatment (POL)
Date received	May 30, 2023
Decision date	Oct 21, 2023
Days to decision	144 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Phenox Limited**
Location	Galway, IE
Contact	Rachel McDaid
510(k) history	4 submissions · 4 cleared · 2019-2025