K222848 pRESET Thrombectomy Device

CLEARED

Jan 20, 2023
121 days to decision

K222848 · Product code: **POL** · Neurology
Source: https://www.510kdatabase.net/k222848/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Neurovascular Mechanical Thrombectomy Device For Acute Ischemic Stroke Treatment (POL)
Date received	Sep 21, 2022
Decision date	Jan 20, 2023
Days to decision	121 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

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

CLINICAL EVIDENCE - NCT03994822

pRESET for Occlusive Stroke Treatment

Status	Completed - *No results published to ClinicalTrials.gov*
Enrollment	340 patients (actual)
Study sites	24 sites
Condition studied	Brain Diseases; Cardiovascular Diseases; Central Nervous System Diseases; Cerebrovascular Disorders; Ischemia; Nervous System Diseases; Pathologic Processes; Stroke, Ischemic; Stroke, Acute; Vascular Diseases
Primary purpose	Treatment
Study type	Interventional
Study design	Parallel
Masking	Single blind
Completion date	May 12, 2022
Sponsor	phenox Inc. (Industry)

Primary outcome

Primary Effectiveness Endpoint: Patients with a Modified Rankin Scale (mRS) </= 2

Secondary outcome

Successful Revascularization measured using the expanded Thrombolysis in Cerebrovascular Infarction (eTICI)

Source: ClinicalTrials.gov / U.S. National Library of Medicine - clinicaltrials.gov/study/NCT03994822