

K253590 Millipede SystemMar 16, 2026
119 days to decisionK253590 · Product code: **NRY** · Neurology
Source: <https://www.510kdatabase.net/k253590/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter, Thrombus Retriever (NRY)
Date received	Nov 17, 2025
Decision date	Mar 16, 2026
Days to decision	119 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Perfuzo, Ltd.
Location	Galway, IE
Contact	Anne-Marie Gannon
510(k) history	9 submissions · 9 cleared · 2022-2026

CLINICAL EVIDENCE - NCT05714501

Millipede AspiRation for Revascularization in Stroke (MARRS) Study

Status	Completed - <i>No results published to ClinicalTrials.gov</i>
Enrollment	246 patients (actual)
Study sites	23 sites
Condition studied	Acute Ischemic Stroke
Primary purpose	Treatment
Study type	Interventional
Study design	Single group
Masking	Open label
Completion date	May 12, 2025
Sponsor	Perfuzo (Industry)

Primary outcome

Proportion of subjects with successful reperfusion, defined as achieving a modified Thrombolysis in Cerebrovascular Infarction (mTICI) score of 2b or greater, after ≥3 passes with the Millipede System without additional therapy.

Source: ClinicalTrials.gov / U.S. National Library of Medicine - clinicaltrials.gov/study/NCT05714501
