

K251357 Esperance pHLO Aspiration SystemJan 15, 2026
260 days to decisionK251357 · Product code: **NRY** · Neurology
Source: <https://www.510kdatabase.net/k251357/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter, Thrombus Retriever (NRY)
Date received	Apr 30, 2025
Decision date	Jan 15, 2026
Days to decision	260 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Phenox, Ltd.
Location	Galway, IE
Contact	Rachel McDaid
510(k) history	3 submissions · 3 cleared · 2022-2026

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