

K211120 ERIC Retrieval DeviceMar 31, 2022
350 days to decisionK211120 · Product code: **NRY** · Neurology
Source: <https://www.510kdatabase.net/k211120/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter, Thrombus Retriever (NRY)
Date received	Apr 15, 2021
Decision date	Mar 31, 2022
Days to decision	350 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	MicroVention, Inc.
Location	Aliso Viejo, CA, US
Contact	Stephanie Onstot
510(k) history	85 submissions · 85 cleared · 2001-2024

CLINICAL EVIDENCE - NCT03776877

Endovascular Treatment in Ischemic Stroke Follow-up Evaluation

Status	Unknown - <i>No results published to ClinicalTrials.gov</i>
Enrollment	4000 patients (estimated)
Study sites	16 sites
Condition studied	Stroke, Acute
Study type	Observational
Completion date	Dec 1, 2022
Sponsor	Hopital Foch (Other)

Primary outcome**Clinical outcome****Secondary outcome**

Efficacy on reperfusion (modified Thrombolysis in Cerebral Infarction (mTICI) 2b/3)

Source: ClinicalTrials.gov / U.S. National Library of Medicine - clinicaltrials.gov/study/NCT03776877