

K181186 Solitare Platinum Revascularization DeviceOct 25, 2018
175 days to decisionK181186 · Product code: **POL** · Neurology
Source: <https://www.510kdatabase.net/k181186/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Neurovascular Mechanical Thrombectomy Device For Acute Ischemic Stroke Treatment (POL)
Date received	May 3, 2018
Decision date	Oct 25, 2018
Days to decision	175 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Micro Therapeutics, Inc. d/b/a ev3 Neurovascular
Location	Lrvine, CA, US
Contact	Ryan Kenney
510(k) history	32 submissions · 32 cleared · 2014-2025

CLINICAL EVIDENCE - NCT01657461**Solitaire™ With the Intention For Thrombectomy as PRIMARY Endovascular Treatment (SWIFT PRIME) Trial**

Status	Completed
Enrollment	196 patients (actual)
Study sites	1 site
Condition studied	Acute Ischemic Stroke
Primary purpose	Treatment
Study type	Interventional
Study design	Parallel
Masking	Open label
Completion date	Jan 1, 2015
Sponsor	Medtronic Neurovascular Clinical Affairs (Industry)

Primary outcome

90-day Global Disability Assessed Via the Blinded Evaluation of Modified Rankin Score (mRS).

Secondary outcome

Death Due to Any Cause at 90 Days

Source: ClinicalTrials.gov / U.S. National Library of Medicine - clinicaltrials.gov/study/NCT01657461