

# K181807 Solitaire 2 Revascularization Device, Solitaire Platinum Revascularization Device (Solitaire Revascularization Device)

Mar 6, 2019  
243 days to decision

K181807 · Product code: POL · Neurology  
Source: <https://www.510kdatabase.net/k181807/>

## SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Neurovascular Mechanical Thrombectomy Device For Acute Ischemic Stroke Treatment (POL)
Date received	Jul 6, 2018
Decision date	Mar 6, 2019
Days to decision	243 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

## APPLICANT

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

## CLINICAL EVIDENCE - NCT02586415

### Endovascular Therapy Following Imaging Evaluation for Ischemic Stroke 3

Status	Terminated
Enrollment	182 patients (actual)
Study sites	40 sites
Condition studied	Stroke, Acute; Cerebral Infarction
Primary purpose	Treatment
Study type	Interventional
Study design	Parallel
Masking	Open label
Completion date	Aug 23, 2017
Sponsor	Gregory W Albers (Other)

#### Primary outcome

The Distribution of Scores on the Modified Rankin Scale (mRS) at Day 90

#### Secondary outcome

Count of Patients With mRS 0-2 at Day 90 as a Measure of Functional Independence

Source: ClinicalTrials.gov / U.S. National Library of Medicine - [clinicaltrials.gov/study/NCT02586415](https://clinicaltrials.gov/study/NCT02586415)