

K203358 Solitaire X Revascularization DeviceMar 1, 2021
105 days to decisionK203358 · Product code: **POL** · Neurology
Source: <https://www.510kdatabase.net/k203358/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Neurovascular Mechanical Thrombectomy Device For Acute Ischemic Stroke Treatment (POL)
Date received	Nov 16, 2020
Decision date	Mar 1, 2021
Days to decision	105 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	Kevin Kong
510(k) history	32 submissions · 32 cleared · 2014-2025

CLINICAL EVIDENCE - NCT02239640

Systematic Evaluation of Patients Treated With Stroke Devices for Acute Ischemic Stroke (STRATIS) Registry

Status	Completed
Enrollment	984 patients (actual)
Study sites	55 sites
Condition studied	Ischemic Stroke
Study type	Observational
Completion date	Oct 7, 2016
Sponsor	Medtronic Neurovascular Clinical Affairs (Industry)

Primary outcome

Number of Participants Assessed for Revascularization With mTICI Grades 2b-3

Secondary outcome

Incidence of Neurological Events of Interest

Source: ClinicalTrials.gov / U.S. National Library of Medicine - clinicaltrials.gov/study/NCT02239640

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