

K193576 Solitaire Platinum Revascularization Device, Solitaire X Revascularization Device (Solitaire Revascularization Device)Nov 20, 2020
333 days to decisionK193576 · Product code: **POL** · Neurology
Source: <https://www.510kdatabase.net/k193576/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Neurovascular Mechanical Thrombectomy Device For Acute Ischemic Stroke Treatment (POL)
Date received	Dec 23, 2019
Decision date	Nov 20, 2020
Days to decision	333 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

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