

K183022 Solitaire 4 Revascularization Device

Jan 29, 2019
89 days to decision

K183022 · Product code: **POL** · Neurology
Source: <https://www.510kdatabase.net/k183022/>

SUBMISSION DETAILS

| | |
|-----------------------|--|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Neurovascular Mechanical Thrombectomy Device For Acute Ischemic Stroke Treatment (POL) |
| Date received | Nov 1, 2018 |
| Decision date | Jan 29, 2019 |
| Days to decision | 89 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 | Helen Chow |
| 510(k) history | 32 submissions · 32 cleared · 2014-2025 |

510k Database - www.510kdatabase.net

Device record: <https://www.510kdatabase.net/k183022/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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