January 29, 2019

Micro Therapeutics, Inc. d/b/a ev3 Neurovascular
Helen Chow, PhD, RAC
Senior Specialist, Regulatory Affairs
9775 Toledo Way
Irvine, California 92618

Re: K183022
Trade/Device Name: Solitaire™ 4 Revascularization Device
Regulation Number: 21 CFR 882.5600
Regulation Name: Neurovascular Mechanical Thrombectomy Device for Acute Ischemic Stroke Treatment
Regulatory Class: Class II
Product Code: POL, NRY
Dated: December 21, 2018
Received: December 26, 2018

Dear Helen Chow:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal

statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Xiaolin Zheng
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for Carlos L. Peña, PhD, MS
Director
Division of Neurological
and Physical Medicine Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K183022

Device Name
Solitaire™ 4 Revascularization Device

Indications for Use *(Describe)*

1. The Solitaire™ Revascularization Device is indicated for use to restore blood flow in the neurovasculature by removing thrombus for the treatment of acute ischemic stroke to reduce disability in patients with a persistent, proximal anterior circulation, large vessel occlusion, and smaller core infarcts who have first received intravenous tissue plasminogen activator (IV t-PA). Endovascular therapy with the device should be started within 6 hours of symptom onset.

2. The Solitaire™ Revascularization Device is indicated to restore blood flow by removing thrombus from a large intracranial vessel in patients experiencing ischemic stroke within 8 hours of symptom onset. Patients who are ineligible for IV t-PA or who fail IV t-PA therapy are candidates for treatment.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(k) Summary - K183022

510(k) Owner:	Micro Therapeutics, Inc. d/b/a ev3 Neurovascular 9775 Toledo Way Irvine, CA 92618 Establishment Registration No. 2029214
Contact Person:	Helen Chow Sr. Specialist, Regulatory Affairs Telephone: (949) 297-5474 E-mail: helen.h.chow@medtronic.com

Date Summary Prepared:	October 30, 2018
Trade Name of Device:	Solitaire™ 4 Revascularization Device
Common Name of Device:	Neurovascular Mechanical Thrombectomy Device for Acute Ischemic Stroke Treatment; Catheter, Thrombus Retriever
Classification of Device:	Class II, 21 CFR 882.5600; 21 CFR 870.1250
Product Code:	POL; NRY
Predicate Device:	Solitaire™ Platinum Revascularization Device (K181186)

Device Description:

The Solitaire™ 4 Revascularization Device is designed to restore blood flow in patients experiencing ischemic stroke due to large intracranial vessel occlusion. The Solitaire™ 4 Revascularization Device is designed for use in the neurovasculature such as the Internal Carotid Artery (ICA), M1 and M2 segments of the middle cerebral artery, basilar, and the vertebral arteries. The distal nitinol portion of the Solitaire™ 4 Revascularization Device facilitates clot retrieval and has Platinum/Iridium radiopaque markers on the proximal and distal ends. The Solitaire™ 4 Revascularization Device also features radiopaque markers along the circumference of the working length of the device. The devices are supplied sterile and are intended for single-use only.

Indications for Use:

1. The Solitaire™ Revascularization Device is indicated for use to restore blood flow in the neurovasculature by removing thrombus for the treatment of acute ischemic stroke to reduce disability in patients with a persistent, proximal anterior circulation, large vessel occlusion, and smaller core infarcts who have first received intravenous tissue plasminogen activator (IV t-PA). Endovascular therapy with the device should be started within 6 hours of symptom onset.
2. The Solitaire™ Revascularization Device is indicated to restore blood flow by removing thrombus from a large intracranial vessel in patients experiencing ischemic stroke within

8 hours of symptom onset. Patients who are ineligible for IV t-PA or who fail IV t-PA therapy are candidates for treatment.

Device Comparison:

A comparison of the technological characteristics of the subject Solitaire™ 4 Revascularization Device and the predicate Solitaire™ Platinum Revascularization Device (K181186) is provided in **Table 1**. The Solitaire™ 4 Revascularization Device is a design modification of the delivery system to Solitaire™ Platinum. Modifying the delivery system allows for all of the sizes (diameters and lengths) of Solitaire™ 4 to fit through a 0.021" inner diameter microcatheter.

Table 1: Device Comparison

	Predicate Solitaire™ Platinum Revascularization Device (K181186)	**Subject Solitaire™ 4 Revascularization Device**	**Rationale for Difference (if applicable)**
Indication for Use	1. The Solitaire™ Revascularization Device is indicated for use to restore blood flow in the neurovasculature by removing thrombus for the treatment of acute ischemic stroke to reduce disability in patients with a persistent, proximal anterior circulation, large vessel occlusion, and smaller core infarcts who have first received intravenous tissue plasminogen activator (IV t-PA). Endovascular therapy with the device should be started within 6 hours of symptom onset. 2. The Solitaire™ Revascularization Device is indicated to restore blood flow by removing thrombus from a large intracranial vessel in patients experiencing ischemic stroke within 8 hours of symptom onset. Patients who are ineligible for IV t-PA or who fail IV t-PA therapy are candidates for treatment.	Same	N/A
Principles of Operation	The device is used in the neurovasculature to restore	Same	N/A

Table 1: Device Comparison			
	Predicate Solitaire™ Platinum Revascularization Device (K181186)	**Subject Solitaire™ 4 Revascularization Device**	**Rationale for Difference (if applicable)**
	blood flow for treatment of acute ischemic stroke		
Dimensions and Materials			
Device Size(s)	4-20-05 mm 4-20-10 mm 4-40-10 mm 6-20-10 mm 6-24-06 mm 6-40-10 mm	4-20-05 mm 4-20-10 mm 4-40-10 mm 6-20-10 mm 6-24-06 mm 6-40-10 mm	Same
Device Materials	Stent: Nitinol Pushwire: Nitinol Markers: 90% Platinum/ 10% Iridium Push-wire shrink Tubing: PTFE Introducer Sheath: PTFE/Grilamid	Same	N/A
Sterilization and Packaging			
Packaging Materials	Stored within dispenser coil, Tyvek pouch, and shipping carton.	Stored within dispenser coil, Tyvek/Nylon pouch, and shipping carton.	The pouch is the only change in the key packaging materials. The Nylon/Tyvek pouch maintains sterility for the labeled shelf of the Solitaire™ 4 device.
Sterilization Method	Ethylene Oxide	Same	N/A
How Supplied	Sterile, Single Use	Same	N/A

Performance Data:

Biocompatibility:

Solitaire™ 4 does not introduce any new materials into the finished device nor the manufacturing processes. The material of the subject Solitaire™ 4 is identical to the material of the predicate Solitaire™ Platinum (K181186). Therefore, no new biocompatibility evaluations were conducted on the subject device. The prior completed biocompatibility evaluations on the predicate device were used to support the biocompatibility profile of the subject device.

The following non-clinical bench tests were performed to support the Solitaire™ 4 device.

Test	Test Method Summary	Conclusions
Total System Length	Total System Length was measured from the distal tip of the distal marker to the proximal tip of the delivery system.	Acceptance criteria met

Test	Test Method Summary	Conclusions
Fluorosafe Marker Length	Fluorosafe marker length was measured from the measurement of the length from the distal tip of the device to distal end of the marker.	Acceptance criteria met
Delivery Force	Delivery force was measured through a representative tortuous anatomical model.	Acceptance criteria met
Re-Sheathing Force	Retrieval force was measured through a representative tortuous anatomical model.	Acceptance criteria met
Particulate	Particulate was evaluated for generation under simulated use in a representative tortuous anatomical model.	Acceptance criteria met
Durability	Durability was evaluated on the ability to withstand simulated use of the device, including delivery, resheathing and retrieval in a representative tortuous model with the appropriate ancillary devices.	Acceptance criteria met
System Tensile	Following simulated use, the tensile force testing is performed to verify the amount of force it takes to detach the device meets the acceptance criteria.	Acceptance criteria met
Torque	Torque testing is performed to verify the stent joint withstands a minimum of one rotation on the proximal wire following simulated use.	Acceptance criteria met
Marker Tensile	Marker tensile strength testing is performed to verify the strength of the laser weld of the Pt/Ir marker coil to the Nitinol distal finger of the device.	Acceptance criteria met

Performance Data - Animal, Clinical:

No clinical or animal testing was performed on the subject device because there is no change in the indications for use or the fundamental scientific technology of the device.

Conclusion:
Bench testing confirmed that the modifications to Solitaire™ 4 met product specifications and do not raise new questions on the safety and effectiveness of the device. Additionally, there are no changes to the indications for use or the fundamental scientific technology of the device. Therefore, the subject Solitaire™ 4 Revascularization Device is substantially equivalent to the predicate Solitaire™ Platinum Revascularization Device.