October 25, 2018

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

Re: K181186
Trade/Device Name: Solitaire Platinum 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: September 25, 2018
Received: September 26, 2018

Dear Helen Chow, Ph.D., RAC:

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 -S

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)*
K181186

Device Name
Solitaire™ Platinum Revascularization Device

Indications for Use *(Describe)*

1. The Solitaire™ Platinum 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™ Platinum 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: K181186

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

Date Summary Prepared:	September 25, 2018
Trade Name of Device:	Solitaire™ Platinum Revascularization Device
Common Name of Device:	Neurovascular Mechanical Thrombectomy Device for Acute Ischemic Stroke Treatment
	Catheter, Thrombus Retriever
Classification of Device:	21 CFR 882.5600 – Class II
	21 CFR 870.1250 – Class II
Product Code(s):	POL
	NRY
Primary Predicate Device:	Solitaire™ 2 Revascularization Device 510(k)#: K162539
Additional Predicate Device(s):	Solitaire™ Platinum Revascularization Device 510(k)#: K153071, K161879, K160641

Device Description:
The Solitaire™ Platinum Revascularization Device is designed to restore blood flow by removing thrombus in patients experiencing ischemic stroke due to large intracranial vessel occlusion. The Solitaire™ Platinum Revascularization Device is designed for use in the neurovasculature such as the internal carotid artery, M1 and M2 segments of the middle cerebral artery, basilar, and the vertebral arteries. The distal, nitinol portion of the device facilitates clot retrieval and features an "overlap-design." The Solitaire™ Platinum Revascularization Device is designed with Platinum/Iridium radiopaque markers on the proximal and distal ends. In addition, the Solitaire™ Platinum Revascularization Device features radiopaque markers along the circumference of the working length. The Solitaire™ Platinum Revascularization Device is supplied sterile and intended for single-use.

The purpose of this submission is to modify the labeling for the subject Solitaire™ Platinum Revascularization Device to increase the number of flow restoration recoveries per device, align the minimum recommended vessel diameter across all models, and to update the list of optional accessories to include a guide catheter (minimum 5F).

Indications for Use:

1. The Solitaire™ Platinum 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™ Platinum 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:

	Primary Predicate Solitaire™ 2 Revascularization Device	Additional Predicate Solitaire™ Platinum Revascularization Device	Subject Solitaire™ Platinum Revascularization Device
Device Classification	Class II, POL/NRY	Class II, NRY	Same as Primary Predicate
Indication for Use (IFU) Statement	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. 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.	The Solitaire™ Platinum Revascularization Device is intended 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 intravenous tissue plasminogen activator (IV t-PA) or who fail IV t-PA therapy are candidates for treatment.	Same as Primary Predicate

Method of Supply	Stored within dispenser coil, Tyvek pouch, and shipping carton	Same	Same
Sterilization Method	Ethylene Oxide	Same	Same
Device Sizes	4-15 4-20 4-40 6-20 6-30	4-20-10 4-40-10 6-20-10 4-20-05 6-24-06 6-40-10	Same as Additional Predicate
Material			
Push Wire	Nitinol	Same	Same
Shrink Tube	PTFE	Same	Same
Proximal Coil	Platinum/Iridium	Same	Same
Marker Band	Platinum/Iridium	Same	Same
Shrink Tube	PTFE	Same	Same
Introducer Sheath	Grilamid PTFE	Same	Same
Stent	Nitinol	Same	Same
Distal Marker Coil	Platinum/Iridium	Same	Same
Body Markers	N/A	Platinum/Iridium	Same as Additional predicate

Aside from the modified labeling, there have been no changes to the subject Solitaire™ Platinum Revascularization Device from the additional predicate Solitaire™ Platinum Revascularization Device (K153071, K161879 and K160641). In addition, the design modifications implemented into the additional predicate Solitaire™ Platinum Revascularization Device have been determined to be substantially equivalent to the primary predicate Solitaire™ 2 Revascularization Device (K162539).

Since the device design, materials, and manufacturing were not changed in the subject 510(k) submission, biocompatibility, sterilization, shelf-life, bench performance data, animal performance data, and clinical performance data were leveraged from the primary and additional predicate devices.

Performance Data – Bench:
The following non-clinical bench testing was leveraged to support the modified labeling for the subject Solitaire™ Platinum Revascularization Device.

Test	Test Method Summary	Results
Durability – Multiple Resheathing Cycles	Durability is performed to demonstrate that the device is able to withstand multiple resheathing cycles through a clinically relevant model.	The Solitaire™ Platinum Revascularization Device met the acceptance criteria for resheathing durability.
Simulated-Use	Simulated-use is performed to ensure the device is subjected to testing (e.g.,	The Solitaire™ Platinum Revascularization Device met the

Test	Test Method Summary	Results
	delivery force) through a clinically relevant model.	individual acceptance criteria for simulated-use.
Tensile Strength (Total System and Marker Band)	Tensile strength is performed to obtain a quantitative measurement for the strength of the total system and the body markers.	The Solitaire™ Platinum Revascularization Device met the acceptance criteria for tensile strength.
Simulated clot retrieval testing	Clot retrieval performance of the subject device with 5F guide catheter was evaluated on multiple clot morphologies in a clinically relevant model.	Clot retrieval performance of the subject device with a 5F guide catheter was substantially equivalent to the predicate testing with balloon guide catheter

Performance Data – Animal:
Non-clinical animal testing was performed to evaluate the safety and usability of the reference Solitaire™ Platinum Revascularization Device in comparison to the predicate Solitaire™ 2 Revascularization Device at both acute and chronic time points in a porcine model. Non-clinical animal testing was performed in accordance with 21 CFR Part 58 for Good Laboratory Practice (GLP) for Non-Clinical Laboratory Studies.

The subject Solitaire™ Platinum Revascularization Device shares same the fundamental scientific technology as the predicate Solitaire™ 2 Revascularization Device and reference Solitaire™ Platinum Revascularization Device. Therefore, additional non-clinical animal testing was not performed for the subject Solitaire™ Platinum Revascularization Device. An analysis of previous non-clinical animal testing was used to support the modified labeling.

Performance Testing – Clinical:
The subject Solitaire™ Platinum Revascularization Device does not change the fundamental scientific technology of the predicate Solitaire™ 2 Revascularization Device.

The subject Solitaire™ Platinum Revascularization Device is substantially equivalent to the predicate Solitaire™ 2 Revascularization Device and does not raise new questions of the safety and effectiveness. A subgroup analysis of the clinical data from SWIFT PRIME was summarized to provide further confirmatory support of the modified labeling.