November 20, 2020

Micro Therapeutics, Inc. d/b/a ev3 Neurovascular
Jennifer Correa, MS, RAC
Program Manager, Regulatory Affairs
9775 Toledo Way
Irvine, California 92618

Re: K193576
Trade/Device Name: Solitaire Platinum Revascularization Device, Solitaire X Revascularization Device (Solitaire 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: October 26, 2020
Received: October 27, 2020

Dear Jennifer Correa:

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/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); 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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). 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 (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

for Naira Muradyan, Ph.D.
Assistant Director
DHT5A: Division of Neurosurgical,
Neurointerventional
and Neurodiagnostic Devices
OHT5: Office of Neurological
and Physical Medicine Devices
Office of Product Evaluation and Quality
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)*
K193576

Device Name
Solitaire™ Platinum Revascularization Device, Solitaire™ X Revascularization Device
(Solitaire™ 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.

3. 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 of the internal carotid artery (ICA) or middle cerebral artery (MCA)-M1 segments with smaller core infarcts (< 70 cc by CTA or MRA, < 25 cc by MR-DWI). Endovascular therapy with the device should start within 6-16 hours of time last seen well in patients who are ineligible for intravenous tissue plasminogen activator (IV t-PA) or who fail IV t-PA therapy.

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(K) Summary **K193576**

510(k) Owner:	Micro Therapeutics, Inc. d/b/a ev3 Neurovascular 9775 Toledo Way Irvine, CA 92618 Establishment Registration No. 2029214
Contact Person:	Jennifer Correa Program Manager, Regulatory Affairs Telephone: (949) 297-5494 E-mail: Jennifer.L.Correa@medtronic.com

Date Summary Prepared:	November 18, 2020	
Trade Name of Device:	Solitaire™ Platinum Revascularization Device, Solitaire™ X Revascularization Device (Solitaire™ Revascularization Device)	
Common Name of Device:	Neurovascular Mechanical Thrombectomy Device for Acute Ischemic Stroke Treatment	Catheter, Thrombus Retriever
Classification:	Class II, 21 CFR 882.5600	Class II, 21 CFR 870.1250
Product Code:	POL	NRY
Primary Predicate Devices:	Solitaire™ Platinum Revascularization Device (K181186); Solitaire™ 4 Revascularization Device (K183022)	
Additional Predicate Devices:	Solitaire™ Platinum Revascularization Device and Solitaire™ 2 Revascularization Device (K181807)	

Device Description:

The Solitaire™ Revascularization Device is designed to restore blood flow in patients experiencing ischemic stroke due to large intracranial vessel occlusion. The Solitaire™ Revascularization Device is intended 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 Solitaire™ Revascularization Device facilitates clot retrieval and has Platinum/Iridium radiopaque markers on the proximal and distal ends and 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.
3. 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 of the internal carotid artery (ICA) or middle cerebral artery (MCA)-M1 segments with smaller core infarcts (< 70 cc by CTA or MRA, < 25 cc by MR-DWI). Endovascular therapy with the device should start within 6-16 hours of time last seen well in patients who are ineligible for intravenous tissue plasminogen activator (IV t-PA) or who fail IV t-PA therapy.

Device Comparison:

A comparison of the technological characteristics of the subject Solitaire™ Revascularization Device and the predicate Solitaire™ 2 Revascularization Device (Solitaire™ Platinum Revascularization Device K181807, K181186; Solitaire™ 4 Revascularization Device K183022) is provided in **Table 1**. This 510(k) is for a labeling modification to reduce the recommended minimum vessel diameter for the subject Solitaire™ Revascularization Device, 4 mm device models. The Indications for Use (IFU) of the subject Solitaire™ Revascularization Device remain unchanged and are identical to the legally marketed additional predicate device. The subject Solitaire™ Revascularization device is identical to the primary predicate Solitaire™ Revascularization Devices, apart from these labeling modifications.

Table 1: Device Comparison

	Primary Predicate Solitaire™ Revascularization Device (K181186, K183022)	**Additional Predicate Solitaire™ Revascularization Device (K181807)**	**Subject Solitaire™ Revascularization Device**
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	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	Same as additional predicate

Table 1: Device Comparison				
	Primary Predicate Solitaire™ Revascularization Device (K181186, K183022)	**Additional Predicate Solitaire™ Revascularization Device (K181807)**		**Subject Solitaire™ Revascularization Device**
	t-PA therapy are candidates for treatment.	t-PA therapy are candidates for treatment. 3. 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 of the internal carotid artery (ICA) or middle cerebral artery (MCA)-M1 segments with smaller core infarcts (< 70 cc by CTA or MRA, < 25 cc by MR-DWI). Endovascular therapy with the device should start within 6-16 hours of time last seen well in patients who are ineligible for intravenous tissue plasminogen activator (IV t-PA) or who fail IV t-PA therapy.		
Principles of Operation	The device is used in the neurovasculature to restore blood flow for treatment of acute ischemic stroke	Same		Same
Vessel Size	2.0 to 4.0 mm (4 mm device) 2.0 to 5.5 mm (6 mm device)	Same		1.5 to 4.0 mm (4 mm device) 2.0 to 5.5 mm (6 mm device)
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	4-15 mm 4-20 mm 4-40 mm 6-20 mm 6-30 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 as Primary Predicate
Device Materials	Stent: Nitinol Pushwire: Nitinol Markers: 90% Platinum/ 10% Iridium Push-wire shrink Tubing: PTFE Introducer Sheath: PTFE/Grilamid	Same		Same
Sterilization and Packaging				
Packaging Materials	Stored within dispenser coil, pouch, and shipping carton.	Same		Same
Sterilization Method	Ethylene Oxide	Same		Same
How Supplied	Sterile, Single Use	Same		Same

Performance Testing - Bench:
The subject Solitaire™ Revascularization device is identical to the primary predicate Solitaire™ Revascularization Devices including device design, materials, manufacturing, packaging, sterilization, and shelf-life. Therefore, previously conducted biocompatibility tests, sterilization validation, and shelf-life were leveraged from the predicate devices. The following non-clinical bench test was performed to support the labeling modification:

Test	Test Method Summary	Conclusions
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
Radial Force	Radial force measured at a minimum vessel diameter.	Acceptance criteria met

Performance Testing – Animal:
No additional animal testing was performed or required to support the labeling modification. Previously conducted animal studies included vessels of appropriate size to support the labeling modifications for minimum recommended vessel diameter.

Performance Testing – Clinical:
To support substantial equivalence of the subject Solitaire™ Revascularization Device, a retrospective analysis of subject vessel size was performed using the STRATIS registry data. This retrospective subgroup analysis demonstrates that the subject Solitaire™ Revascularization 4 mm device, with vessel diameters of 1.5 to 2.0 mm, has similar clinical performance and safety profile compared to the predicate Solitaire™ Revascularization 4 mm device.

Summary of Substantial Equivalence:
There is no change to the Indication for Use Statements or design for the Solitaire™ Revascularization Device in comparison to the legally marketed predicate device. The additional bench testing, existing animal testing and the retrospective vessel diameter analysis demonstrates that the labeling modification does not raise any new or different questions of safety or effectiveness of the Solitaire™ Revascularization Device. The information provided in this submission supports a determination of substantial equivalence for the Solitaire™ Revascularization Device