March 1, 2021

Micro Therapeutics, Inc. d/b/a ev3 Neurovascular
Kevin Kong, M.Sc., RAC
Principal Regulatory Affairs Specialist
9775 Toledo Way
Irvine, California 92618

Re: K203358
Trade/Device Name: Solitaire X 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: January 28, 2021
Received: January 29, 2021

Dear Kevin Kong:

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,

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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K203358

Device Name
Solitaire™ X Revascularization Device

Indications for Use *(Describe)*

1. The Solitaire™ X 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™ X 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™ X 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 – K203358

510(k) Owner:	Micro Therapeutics, Inc. d/b/a ev3 Neurovascular 9775 Toledo Way Irvine, CA 92618 Establishment Registration No. 2029214
Contact Person:	Kevin Kong, M.Sc., RAC Principal Regulatory Affairs Specialist Telephone: (949) 837-3700 E-mail: kevin.kong2@medtronic.com

Date Summary Prepared:	February 25, 2021
Trade Name of Device:	Solitaire™ X Revascularization Device
Common Name of Device:	POL: Neurovascular Mechanical Thrombectomy Device for Acute Ischemic Stroke Treatment NRY: Catheter, Thrombus Retriever
Classification of Device:	Class II, 21 CFR 882.5600; 21 CFR 870.1250
Product Code:	POL; NRY
Predicate Device:	Primary Predicate Device: Solitaire™ 4 Revascularization Device (K183022) Additional Predicate Device: Solitaire™ 2 Revascularization Device, Solitaire™ Platinum Revascularization Device (Solitaire™ Revascularization Device) (K181807)

Device Description

The subject 3 mm Solitaire™ X Revascularization Device is designed to restore blood flow in patients experiencing ischemic stroke due to large intracranial vessel occlusion. The subject 3 mm Solitaire™ X 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 subject 3 mm Solitaire™ X Revascularization Device facilitates clot retrieval and has Platinum/Iridium radiopaque markers on the proximal and distal ends. The subject 3 mm Solitaire™ X 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™ X 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™ X 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™ X 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 device, Solitaire™ X Revascularization Device - 3 mm devices and the predicate Solitaire™ 4 Revascularization Device - 4 mm and 6 mm devices (K183022) is provided in Table 1. The subject 3 mm Solitaire™ X Revascularization Device is a line extension of the existing Solitaire™ 4 Revascularization Device (cleared under K183022).

Table 1: Device Comparison			
	Primary Predicate **Solitaire™ 4 Revascularization Device** **(K183022)**	**Additional Predicate** **Solitaire™ Platinum, Solitaire™ 2 Revascularization Devices** **(K181807)**	**Subject Device** **Solitaire™ X Revascularization Device**
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.	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.	Same as the Additional Predicate - Solitaire™ Platinum, Solitaire™ 2 Revascularization Devices (K181807)
Principles of Operation	The device is used in the neurovasculature to restore blood flow for treatment of acute ischemic stroke.	Same	Same
Device Size(s)	4-20-05 mm 4-20-10 mm	Solitaire™ 2: 4-15 mm	3-20-10 mm 3-40-10 mm

Table 1: Device Comparison			
	Primary Predicate **Solitaire™ 4 Revascularization Device (K183022)**	**Additional Predicate** **Solitaire™ Platinum, Solitaire™ 2 Revascularization Devices (K181807)**	**Subject Device** **Solitaire™ X Revascularization Device**
	4-40-10 mm 6-20-10 mm 6-24-06 mm 6-40-10 mm	4-20 mm 4-40 mm 6-20 mm 6-30 mm Solitaire™ Platinum: 4-20-05 mm 4-20-10 mm 4-40-10 mm 6-20-10 mm 6-24-06 mm 6-40-10 mm	
Device Materials	Stent: Nitinol Pushwire: Nitinol Markers:90%Platinum/10%Iridium Push-wire shrink Tubing: PTFE Introducer Sheath: PTFE/Grilamid L25	Same	Stent: Same Pushwire: Same Markers: Same Push-wire shrink Tubing: Same Introducer Sheath: Marlex 5502/ Orevac 18300/ Grilamid L25
Packaging Materials	Stored within dispenser coil, Tyvek/Nylon pouch, and shipping carton.	Stored within dispenser coil, Tyvek pouch, and shipping carton.	Same as the primary predicate
Sterilization Method	Ethylene Oxide	Same	Same
Distal finger markers	Platinum/Iridium Coils or Bands	Same	Platinum/Iridium Bands

Performance Data

Biocompatibility:

There are minor material differences in the introducer sheath for the subject 3 mm Solitaire™ X Revascularization Device from the previously cleared Solitaire™ 4 Revascularization Device – 4 mm and 6mm devices (K183022). A risk-based approach assessing the materials and manufacturing of the introducer sheath was used to evaluate biocompatibility. The minor differences were concluded to not change the biocompatibility profile for the introducer sheath.

The following non-clinical bench tests were performed to support the subject 3 mm Solitaire™ X Revascularization Device:

Table 2: Performance Testing

Test	Test Method Summary	Conclusions
Delivery Force	The delivery force is performed to verify the Maximum delivery force through microcatheters to the M2 section of a representative tortuous anatomical model.	Acceptance criteria met
Resheathing Test	The resheathing test is performed to verify that the device is able to be resheathed into microcatheters in the M2 section of a representative tortuous anatomical model.	Acceptance criteria met
System Lengths	The device system length from the proximal end of the pushwire to the proximal end of the keyhole marker band and total system length in sheath.	Acceptance criteria met
Durability and Reusability Test	The reusability and durability test is performed to verify that the device is able to be reliably deployed and resheathed into a microcatheter for four times for four passes in a clinically relevant tortuosity model.	Acceptance criteria met
System Tensile Strength Test	System tensile strength test is performed following simulated use via delivery through a microcatheter in a clinically relevant tortuosity model.	Acceptance criteria met
Distal Marker Tensile Test and Body Marker Tensile Test	Marker band tensile strength test is performed following simulated use via delivery through a microcatheter in a clinically relevant tortuosity model.	Acceptance criteria met
Torque Test	Torque testing is performed to verify if the stent joint can withstand a minimum of one rotation in a clinically relevant tortuosity model.	Acceptance criteria met
Radial Outward Force	The maximum radial outward force (ROF) is measured to specification.	Acceptance criteria met

Table 2: Performance Testing		
Test	**Test Method Summary**	**Conclusions**
Stent Outer Diameter	The average device diameter is measured post simulated use testing.	Acceptance criteria met
Particulate Test	Particulates generated during simulated use (including multiple deployment cycling).	Acceptance criteria met
Fluorosafe Marker Distance	The distance from the distal tip of the device subassembly to the distal end of the fluorosafe marker in-sheath is measured.	Acceptance criteria met

Performance Data- Animal:

Non-clinical animal testing was performed to evaluate the safety of the 3mm Solitaire™ X Revascularization Device in a porcine model at sub-acute and 30-day (chronic) time points. The study was conducted in compliance with applicable requirements in the GLP regulation (21 CFR Part 58). The safety and usability results from the sub-acute and chronic animal study suggest that the subject 3mm Solitaire™ X Revascularization Device is substantially equivalent to the predicate Solitaire™ 4 Revascularization Device (K183022).

Clinical:

To support substantial equivalence of the subject 3mm Solitaire™ X Revascularization Device, a retrospective analysis of vessel sizes was performed using the STRATIS registry data, previously submitted in K193576.

Conclusion:

Testing confirmed that the subject 3 mm Solitaire™ X Revascularization Device met product specifications and the differences in design did not raise new questions of safety and effectiveness. Additionally, there are no changes to the fundamental scientific technology of the device.

Therefore, the information provided in this submission supports a determination of substantial equivalence for the subject 3 mm Solitaire™ X Revascularization Device to the primary predicate Solitaire™ 4 Revascularization Device (K183022) and additional predicate devices - Solitaire™ Platinum Revascularization Device, Solitaire™ 2 Revascularization Device (K181807).