DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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March 8, 2017

Micro Therapeutics, Inc. d/b/a ev3 Neurovascular
Jennifer Correa
Senior Regulatory Affairs Specialist
9775 Toledo Way
Irvine, California 92618

Re: K160641
Trade/Device Name: Solitaire™ Platinum Revascularization Device (6x40 mm)
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous Catheter
Regulatory Class: Class II
Product Code: NRY
Dated: February 16, 2017
Received: February 21, 2017

Dear Ms. 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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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 the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

William J. Heetderks -S

Digitally signed by William J. Heetderks -S
DN: c=US, o=U.S. Government, ou=HHS, ou=FDA, ou=People, 0.9.2342.19200300.100.1.1=0010149848, cn=William J. Heetderks -S
Date: 2017.03.08 16:48:39 -05'00'

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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K160641

Device Name
Solitaire™ Platinum Revascularization Device (6x40 mm)

Indications for Use *(Describe)*
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.

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.

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510(k) Summary	**K160641**
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 Senior Specialist, Regulatory Affairs Telephone: (949) 297-9563 E-mail: Jennifer.L.Correa@medtronic.com
Date Summary Prepared:	March 1, 2017
Trade Name of Device:	Solitaire™ Platinum Revascularization Device (6x40 mm)
Common Name of Device:	Catheter, Thrombus Retriever
Classification of Device:	21 CFR 870.1250 – Class II
Product Code:	NRY
Predicate Device:	Solitaire™ Platinum Revascularization Device 510(k)#: K153071
Performance Data:	The following non-clinical bench testing and confirmatory clinical data supports the subject 6-40-10 Solitaire™ Platinum Revascularization Device: • Total System Length • Marker-to-Marker Length • Delivery Force • Resheathing Force • Multiple Resheathing Durability • Body Finger Marker Coil Tensile • Radial Force • Radiopacity • Ease of Use (Fluorosafe Marker Location) • Particulate • Leveraged confirmatory clinical data using the cleared 4x40 Solitaire devices
Conclusion:	The materials of construction, design, and manufacturing/ packaging processes for the subject 6-40-10 Solitaire™ Platinum Revascularization Device are identical to the predicate Solitaire™ Platinum Revascularization Device (K153071) therefore; biocompatibility, sterilization, packaging, and shelf life validations have been leveraged or adopted. Non-clinical animal testing was performed to demonstrate safety, effectiveness, and

usability of the subject 6-40-10 Solitaire™ Platinum Revascularization Device. Non-clinical bench and animal testing confirmed that the subject 6-40-10 Solitaire™ Platinum Revascularization Device does not introduce new risks or increase existing risks. Confirmatory clinical data using the cleared 4x40 Solitaire devices (predicate 4-40-10 Solitaire™ Platinum and reference 4-40 Solitaire™ 2) was leveraged to support substantial equivalence of the subject 6-40-10 Solitaire™ Platinum Revascularization Device. The subject Solitaire™ Platinum Revascularization Device should be determined to be substantially equivalent to the predicate Solitaire™ Platinum Revascularization Device (K153071) based on non-clinical bench and animal testing, confirmatory clinical data, similarities in design, principles of operation, and indications for use.

Device Description:
The subject 6-40-10 Solitaire™ Platinum Revascularization Device is designed to restore blood flow 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 (ICA), M1 and M2 segments of the middle cerebral artery, basilar, and the vertebral arteries. The distal nitinol portion of the Solitaire™ Platinum Revascularization Device facilitates clot retrieval. The Solitaire™ Platinum Revascularization Device has Platinum Iridium radiopaque markers on the working cell length, proximal and distal ends. The subject Solitaire™ Platinum Revascularization Device is a portfolio expansion to the predicate Solitaire™ Platinum Revascularization Device (K153071).

Indications for Use:
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.

Device Comparison:
The table below provides a comparison of the technological characteristics associated with the portfolio expansion of the subject 6-40-10 Solitaire™ Platinum Revascularization Device and the predicate Solitaire™ Platinum Revascularization Device (K153071).

	Predicate Device Solitaire™ Platinum Revascularization Device (K153071)	Subject Device 6-40-10 Solitaire™ Platinum Revascularization Device	Rationale for Difference (if applicable)
Indication for Use	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	N/A
Principles of Operation	The device is used in the neurovasculature to restore blood flow by removing thrombus.	Same	N/A
Method of Supply	Stored within dispenser coil, Tyvek pouch, and shipping carton.	Same	N/A
Sterilization Method	Ethylene Oxide	Same	N/A

	Predicate Device Solitaire™ Platinum Revascularization Device (K153071)	Subject Device 6-40-10 Solitaire™ Platinum Revascularization Device	Rationale for Difference (if applicable)
Device Size(s)	4-20-10 4-40-10 6-20-10	6-40-10	The subject 6-40-10 Solitaire™ Platinum Revascularization Device shares similar technological characteristics to the predicate **6**-20-10 (6 mm stent diameter) and the 4-**40**-10 (40 mm stent length) of the predicate Solitaire™ Platinum Revascularization Devices. Bench testing has demonstrated that the subject 6-40-10 Solitaire™ Platinum Revascularization Device is within the existing ranges of the 4x40 Solitaire devices for device length, radial outward force and delivery / resheathing forces.
Materials			
Stent	Nitinol.	Same	N/A
Push-wire	Nitinol.	Same	N/A
Distal Marker Coil	90% Platinum/ 10% Iridium	Same	N/A
Body Finger Marker Coil	90% Platinum/ 10% Iridium	Same	N/A
Push-wire Shrink Tubing	PTFE	Same	N/A
Introducer Sheath	PTFE/Grilamid	Same	N/A

Sterilization and Shelf Life:
The subject 6-40-10 Solitaire™ Platinum Revascularization Device is sterilized using the identical validated, Ethylene Oxide (EO) sterilization cycle as the predicate Solitaire™ Platinum Revascularization Device (K153071). The materials of construction, design, manufacturing process, packaging, and sterile load configurations are identical to the predicate Solitaire™ Platinum Revascularization Device (K153071). Therefore, no additional sterilization validation testing is required.

The subject 6-40-10 Solitaire™ Platinum Revascularization Device and subsequent packaging remain functional and maintain sterility for up to two (2) years. The materials

of construction, design, manufacturing process, packaging, and sterile load configurations are identical to the predicate Solitaire™ Platinum Revascularization Device (K153071). Therefore, no additional shelf life validation testing is required.

Biocompatibility:
The subject 6-40-10 Solitaire™ Platinum Revascularization Device does not introduce any new materials into the finished device nor the manufacturing processes. The material of the subject 6-40-10 Solitaire™ Platinum Revascularization Device is identical to the material of the predicate Solitaire™ Platinum Revascularization Device (K153071). Biocompatibility data for the Solitaire device family was tested for the Solitaire™ FR Revascularization Device. The biocompatibility data for the Solitaire™ FR was adopted for the subject 6-40-10 Solitaire™ Platinum Revascularization Device. A summary of the biocompatibility testing completed for the Solitaire™ FR Revascularization Device includes:

Test Category	Test Description	Method	Acceptance Criteria	Conclusion
Cytotoxicity	L929 MTT Cytotoxicity	ISO 10993-5	Viability is ≥70%.	Acceptance criteria met
Sensitization	Guinea Pig Maximization Sensitization	ISO 10993-10	Test article does not elicit a sensitization response.	Acceptance criteria met
Irritation	Intracutaneous Irritation Test	ISO 10993-10	Differences in the mean test and control scores of the extract dermal observations are < 1.0.	Acceptance criteria met
Acute Systemic Toxicity	Acute Systemic Injection Test	ISO 10993-11	No abnormal clinical signs and weight loss in excess of 10%.	Acceptance criteria met
	Materials Mediated Rabbit Pyrogen		Temperature rise ≥0.5ºC	

Test Category	Test Description	Method	Acceptance Criteria	Conclusion
Hemo-compatibility	Hemolysis	ISO 10993-4	No significant differences between the test article extract and negative control article results. The test article is considered non-hemolytic	Acceptance criteria met
	Partial Thromboplastin Time		Clotting times are similar to the negative control and the reference material (HDPE) indicating the device materials are not an activator of the intrinsic coagulation pathway.	
	Platelet and Leukocyte Count		Test article does not adversely affect the platelet and leukocyte components of the blood compared to the reference material.	
	Complement Activation C3a and SC5b-9 Assay		Levels of C3a and SC5b-9 are comparable and less than the positive control.	
	Thrombosis		Thrombo-resistance properties are acceptable in clinical use.	
Genotoxicity	Bacterial Mutagenicity Test	ISO 10993-3	Test article is considered non-mutagenic	Acceptance criteria met
	In-vitro Mouse Lymphoma Assay		Test article is considered non-mutagenic	
	In-vivo Mouse Micronucleus Assay		Test article is considered non-mutagenic	

Performance Data – Bench:
A summary of the non-clinical bench testing performed for the subject 6-40-10 Solitaire™ Platinum Revascularization Device is summarized in the table below.

Test Description	Method	Acceptance Criteria	Conclusion
Total System Length	Total system length was measured from the distal tip of the distal marker to the proximal tip of the delivery system.	The stent length should be adequate for its intended use for delivery via standard microcatheters.	Acceptance criteria met
Marker-to-Marker Length	Marker-to-marker length is representative of the total stent length. Total stent length was measured 100% in process.	The stent length should be adequate for its intended use for delivery via standard microcatheters.	Acceptance criteria met
Delivery Force	Delivery force was measured through a representative tortuous anatomical model.	The stent must be below delivery force specification.	Acceptance criteria met
Resheathing Force	Resheathing force was measured through a representative tortuous anatomical model.	The stent must be below re-sheathing force specification.	Acceptance criteria met
Multiple Resheathing Durability	Multiple resheathing durability was evaluated on the ability to withstand delivery and withdrawal forces in a representative tortuous model beyond the recommended number of passes and re-sheathings allowed per the Instructions for Use.	The stent must be able to be deployed and resheathed up to four times.	Acceptance criteria met
Body Finger Marker Coil Tensile	Body finger marker coil tensile was performed to verify the strength of the laser weld of the Platinum/Iridium marker coil to the Nitinol body finger.	The body finger marker coil tensile should be greater than or equal to existing tensile strength specification.	Acceptance criteria met

Test Description	Method	Acceptance Criteria	Conclusion
Radial Force	Radial force was measured 100% in process.	The stent must be within existing radial force specification.	Acceptance criteria met
Radiopacity	Radiopacity was verified by both a material and dimensional analyses.	The radiopaque body markers must be visible using standard catheter laboratory equipment.	Acceptance criteria met
Ease of Use (Fluorosafe Marker Location)	Ease of use (fluorosafe marker location) was measured from the distal tip of the distal marker to the distal end of the fluorosafe marker.	Less required fluoroscopy is better than more required fluoroscopy.	Acceptance criteria met
Particulate	Particulate was evaluated for generation under simulated use in a representative tortuous anatomical model.	The stent must not generate clinically unacceptable particulate.	Acceptance criteria met

Performance Data – Animal:
Non-clinical animal testing was conducted to verify the performance of the subject 6-40-10 Solitaire™ Platinum Revascularization Device. Non-clinical animal testing was conducted to verify the subject 6-40-10 Solitaire™ Platinum Revascularization Device is safe and effective in an *in-vivo* Yorkshire cross swine model. Four (4) of the following eight (8) proposed target sites were evaluated:

- Right Vertebral
- Left Vertebral
- Right Internal Thoracic
- Left Internal Thoracic
- Right Costocervical
- Left Costocervical
- Renal
- Ascending Pharyngeal

Please note the renal and ascending pharyngeal are considered alternative back-up sites depending on the size of the swine, distal target zone diameter, length, consistency of vessel diameter, and the ability to harvest the vessel post procedure.

Non-clinical animal testing was evaluated at 0-day (acute) and 30-day (chronic) time points. The non-clinical animal testing was designed to show no-clinical inferiority between the control 6-30 Solitaire™ 2 Revascularization Device and the test 6-40-10 Solitaire™ Platinum Revascularization Device. Non-clinical animal testing evaluated the following biological responses of vascular tissue specific to safety:

- Luminal Thrombus
- Endothelial Cell Coverage
- Inflammation
- Fibrin
- Medial Smooth Muscle Cell (SMC) Loss
- Disruption of the Internal Elastic Lamina (IEL) and External Elastic Lamina (EEL)
- Adventitia
- Neointimal Hyperplasia
- Elastic Fiber Separation
- Lumen Area Reduction

Performance Testing – Clinical:

Type of data

A clinical study was not performed for the subject 6-40-10 Solitaire™ Platinum Revascularization Device. Confirmatory clinical data using the cleared 4x40 Solitaire devices (predicate 4-40-10 Solitaire™ Platinum and reference 4-40 Solitaire™ 2) was leveraged to support substantial equivalence of the subject 6-40-10 Solitaire™ Platinum Revascularization Device. Leveraging of the 4x40 Solitaire device confirmatory clinical data is appropriate as the subject 6-40-10 Solitaire™ Platinum Revascularization Device is within the existing ranges of the 4x40 Solitaire devices for device length, radial outward force and delivery / resheathing forces. The confirmatory 4x40 Solitaire clinical data was collected as part of the **S**ystematic Evaluation of Patients **TR**eated with Neurothrombectomy Devices for **A**cu**T**e **I**schemic**S**troke (STRATIS) Registry.

STRATIS Registry Design

A prospective, multi-center, non-randomized, observational registry evaluating the use of Covidien market-released neurothrombectomy devices in patients diagnosed with an acute ischemic stroke due to large intracranial vessel occlusion. The study used an independent Clinical Events Committee for adverse event adjudication and an independent Core Lab for procedural image assessment.

Sample Size

Under the STRATIS Registry, 984 patients were enrolled that were treated with a Medtronic neurothrombectomy device at the discretion of treating physicians and as part of hospital standard practice at 55 sites within the United States. Of the 984 patients treated, a total of 296 were treated using only the cleared 4x40 device. Major patient eligible criteria for consent and enrollment into the Registry were to be treated with the Solitaire device within 8 hours of symptom onset.

Confirmatory Clinical Data

The confirmatory clinical data leveraged from the STRATIS Registry 4x40 group included baseline demographics, safety data and performance data and showed that the cleared 4x40 Solitaire device has a similar clinical performance and safety profile to other cleared Solitaire device dimensions.

STRATIS Registry 4x40 Subgroup Confirmatory Clinical Data	
Baseline Demographics	
Age (years)	66.4 ± 15.2 (296) 67.0 (58.0, 77.0)
NIHSS at baseline	16.8 ± 5.5 (296) 16.0 (12.0, 21.0)
Male Gender	51.4% (152/296)
Safety Data	
Symptomatic ICH	2.8% (7/252)
Mortality at 90 days	16.2% (48/296)
Performance Data	
Successful revascularization (TICI 2b-3)	90.4% (227/251)
Functional Independence (mRS 0-2) at 90 days	60.3% (167/277)

Device Related Serious Adverse Events (SAEs)

STRATIS Registry 4x40 Subgroup Device-Related SAEs	
Study Device-Related SAEs	0.3% (1/296) [1]**

** Subarachnoid hemorrhage

Conclusion

Non-clinical bench, animal testing and the confirmatory clinical data demonstrated that the subject 6-40-10 Solitaire™ Platinum Revascularization Device is substantially equivalent to the predicate Solitaire™ Platinum Revascularization Device (K153071) and does not raise new questions of the safety and effectiveness of the device. Additionally, there are no changes to the indications for use or the fundamental scientific technology of the Solitaire™ Platinum Revascularization Device.