November 14, 2018

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

Re: K182101
Trade/Device Name: Riptide™ Aspiration System (React™ 71 Catheter)
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous Catheter
Regulatory Class: Class II
Product Code: NRY
Dated: October 12, 2018
Received: October 15, 2018

Dear Ryan Kenney:

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)*
K182101

Device Name
Riptide™ Aspiration System (React™ 71 Catheter)

Indications for Use *(Describe)*
The Riptide™ Aspiration System is intended for use in the revascularization of patients with acute ischemic stroke secondary to intracranial large vessel occlusive disease (within the internal carotid, middle cerebral – M1 and M2 segments, basilar, and vertebral arteries) 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: K182101

510(k) Owner:	Micro Therapeutics, Inc. d/b/a ev3 Neurovascular 9775 Toledo Way Irvine, CA 92618 Establishment Registration No.: 2029214
Contact Person:	Ryan Kenney Senior Regulatory Affairs Specialist Telephone: (949) 297-5489 Email: ryan.j.kenney@medtronic.com

Date Summary Prepared:	October 12, 2018
Trade Name of Device:	Riptide™ Aspiration System (React™ 71 Catheter)
Common Name of Device:	Catheter, Thrombus Retriever
Review Panel:	Neurology
Product Code:	NRY
Regulation Number:	21 CFR 870.1250
Regulation Name:	Percutaneous Catheter
Device Classification:	Class II
Predicate Device:	Penumbra System® (ACE 68 Reperfusion Catheter) 510(k)#: K161064
Additional Predicate Device:	Riptide™ Aspiration System (React™ 68 Catheter) 510(k)#: K180705

Device Description:
The React™ 71 Catheter is a single lumen, flexible, variable stiffness composite catheter with a nitinol structure that is jacketed with a durable polymer outer layer. A lubricious, polytetrafluoroethylene and Engage liner is used to create a structure that has both proximal stiffness and distal flexibility. The React™ 71 Catheter is also designed with an encapsulated radiopaque distal platinum-iridium markerband which is used for visualization under fluoroscopy. The React™ 71 Catheter is introduced into the vasculature through the split y-introducer sheath.

The proximal end of the React™ 71 Catheter is designed with a thermoplastic elastomer strain relief and a clear hub. The distal end of the React™ 71 Catheter is designed with a hydrophilic coating. The React™ 71 Catheter is navigated to the intended treatment site and positioned proximal to the site of occlusion.

Indications for Use:
The Riptide™ Aspiration System is intended for use in the revascularization of patients with acute ischemic stroke secondary to intracranial large vessel occlusive disease (within the internal carotid, middle cerebral – M1 and M2 segments, basilar, and vertebral arteries) 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:

	Penumbra System® (ACE 68 Reperfusion Catheter) (K161064)	Riptide™ Aspiration System (React™ 68 Catheter) (K180705)	Riptide™ Aspiration System (React™ 71 Catheter) (K182101)
Indication for Use (IFU) Statement	The Penumbra System® is intended for use in the revascularization of patients with acute ischemic stroke secondary to intracranial large vessel occlusive disease (within the internal carotid, middle cerebral – M1 and M2 segments, basilar, and vertebral arteries) within 8 hours of symptom onset.	The Riptide™ Aspiration System is intended for use in the revascularization of patients with acute ischemic stroke secondary to intracranial large vessel occlusive disease (within the internal carotid, middle cerebral – M1 and M2 segments, basilar, and vertebral arteries) 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 K180705
Materials			
Proximal Hub	Grilamid™	Trogamid®	Same as K180705
Strain Relief (Hub Sleeve)	Grilamid™	DynaFlex®	Same as K180705
Strain Relief	304 Stainless Steel	N/A	Same as K180705
Inner Diameter Band	Polyolefin, PET Yellow (Black Ink)		
Liner	PTFE	Same as K161064	Polyolefin, PTFE
Braid Reinforcement	N/A	Nitinol	Same as K180705
Coil Reinforcement	304V Stainless Steel Nickel (55%)/Titanium (45%)	Nitinol	Same as K180705

	Penumbra System® (ACE 68 Reperfusion Catheter) (K161064)	Riptide™ Aspiration System (React™ 68 Catheter) (K180705)	Riptide™ Aspiration System (React™ 71 Catheter) (K182101)
Proximal Extrusions	Vestamid® Pebax® 72D	Grilamid™ Pebax® 45D Pebax® 55D Pebax® 63D Pebax® 72D	Polyamide Polyolefin Polyurethane
Distal Extrusions	Pebax® 35D Pebax® 40D Pebax® 55D Pebax® 63D Pellathane® 80A Tecoflex® 80A	Pebax® 25D Pebax® 35D	
Extrusion Colorants	Clear/Natural or Purple	Clear/Natural or Green	Same as K180705
Marker Band	Platinum (90%)/ Iridium (10%)	Same	Same
Coating	SRDX Harmony	Surmodics Serene®	Same as K180705
Dimensions			
Working Length	132 cm	Same	Same
Proximal Inner Diameter (ID)	0.068” (Min.)	0.068” (Min.)	0.071”
Proximal Outer Diameter (OD)	0.084” (Max.)	0.083” (Max.)	0.0855” (Max.)
Distal ID	0.068” (Min.)	0.068” (Min.)	0.071”
Distal OD	0.084” (Max.)	0.083” (Max.)	0.0855” (Max.)
Coating Length	30cm	40cm	Same as K180705
Tip Shape	Straight	Same	Same
Accessories			
Peelable Sheath	PTFE	Same	Same

	Penumbra System® (ACE 68 Reperfusion Catheter) (K161064)	Riptide™ Aspiration System (React™ 68 Catheter) (K180705)	Riptide™ Aspiration System (React™ 71 Catheter) (K182101)
Rotating Hemostasis Valve	Polycarbonate Silicone O-Ring	N/A	Same as K180705
Shaping Mandrel	0.038” OD Stainless Steel		
Packaging			
Carton	SBS Paperboard	Same	Same as K180705
Packaging Card	Polyethylene		
Packaging Hoop	Polyethylene		
Packaging Tray	Polyethylene Terephthalate Polystrene	N/A	
Pouch	Polyester Polyethylene Tyvek®	Nylon Tyvek®	
Other			
Shelf Life	8 Months	3 Months	Same as K180705
Sterilization	Ethylene Oxide (EO)	Same	Same
Use	Single Use, Disposable		

Biocompatibility:
Biocompatibility was conducted for the React™ 71 Catheter. The React™ 71 Catheter is categorized as a limited exposure (< 24 hours), external communicating device contacting circulating blood. The following biocompatibility was conducted for the React™ 71 Catheter:

Test Description	Results	Conclusions
Cytotoxicity (Elution Method)	The test article extract showed no evidence of causing cell lysis or toxicity and had a Grade 0 (No Reactivity). The test article extract met the requirements of the test since the grade was < Grade 2 (Mild Reactivity).	The React™ 71 Catheter is considered non-cytotoxic.
Sensitization (Guinea Pig Maximization Test)	The test article extracts showed no evidence of causing delayed dermal contact sensitization in the guinea pig.	The React™ 71 Catheter does not elicit a sensitization response.
Irritation (Intracutaneous Reactivity)	The test article met the requirements of the test since the difference between each test article extract overall mean score and corresponding control extract overall mean score was 0.0 and 0.2 for the Sodium Chloride and Sesame Oil test article extracts, respectively.	The React™ 71 Catheter is considered a non-irritant.
Acute Systemic Toxicity (Systemic Toxicity)	There was no mortality or evidence of systemic toxicity from the extracts injected into mice.	The React™ 71 Catheter does not indicate signs of toxicity.
Hemocompatibility (Hemolysis)	The hemolytic index for the test article in direct contact with blood was 0.8%, and the hemolytic index for the test article extract was 0.0%.	The React™ 71 Catheter is considered non-hemolytic.

Test Description	Results	Conclusions
Hemocompatibility (Complement Activation)	The concentration of SC5b-9 in the test article was not statistically higher than the activated normal human serum control or the negative control. The test article was statistically lower than the sponsor provided control article.	The React™ 71 Catheter is not considered to be potential activator of the complement system.
Hemocompatibility (Thrombogenicity – Canine Model)	The control article was evaluated and determined to have a mean score of 2.0. The test article was evaluated and determined to have a mean score of 1.7 after four (4) hours (±30 minutes) without systemic anticoagulation.	The React™ 71 Catheter demonstrates lower thrombogenic potential in arterial vessels compared to the ACE 68 Reperfusion Catheter.
Pyrogenicity (Material Mediated)	Not a single animal showed a temperature rise of 0.5°C or more above its baseline temperature. The total rise of the rabbits' temperature during the three (3) hours was 0.0°C.	The React™ 71 Catheter is considered non-pyrogenic.

The React™ 71 Catheter has been evaluated to meet requirements specified in ISO 10993-1.

Performance Data – Bench:
Non-clinical bench testing was leveraged and conducted to evaluate the performance of the React™ 71 Catheter.

The following non-clinical bench testing was leveraged for the React™ 71 Catheter:

Test	Test Method Summary	Results
Microbial		
Ethylene Oxide Residual	The React™ 71 Catheter was evaluated per ISO 10993-7.	The React™ 71 Catheter met the acceptance criteria for ethylene oxide residual.
Ethylene Chlorohydrin Residual	The React™ 71 Catheter was evaluated per ISO 10993-7.	The React™ 71 Catheter met the acceptance criteria for ethylene chlorohydrin residual.
Bioburden Recovery	The React™ 71 Catheter was evaluated per ISO 11737-1.	The React™ 71 Catheter met the acceptance criteria for bioburden recovery.

Test	Test Method Summary	Results
Bacterial Endotoxin	The React™ 71 Catheter was evaluated per ANSI/AAMI ST72 and USP <161>.	The React™ 71 Catheter met the acceptance criteria for bacterial endotoxin.
Packaging		
Visual Inspection	The React™ 71 Catheter was evaluated per ASTM F1886.	The React™ 71 Catheter met the acceptance criteria for visual inspection.
Bubble Leak	The React™ 71 Catheter was evaluated per ASTM F2096.	The React™ 71 Catheter met the acceptance criteria for bubble leak.
Seal Strength	The React™ 71 Catheter was evaluated per ASTM F88.	The React™ 71 Catheter met the acceptance criteria for seal strength.

The following non-clinical bench testing was conducted for the React™ 71 Catheter:

Test	Test Method Summary	Results
Microbial		
Bioburden	The React™ 71 Catheter was evaluated per ISO 11737-1.	The React™ 71 Catheter met the acceptance criteria for bioburden.
Performance		
Visual Inspection	The React™ 71 Catheter was inspected under x2.5 magnification.	The React™ 71 Catheter met the acceptance criteria for visual inspection.
Dimensional Measurements	The proximal ID, distal, ID, proximal OD, distal OD, usable length, total length, coating length, and distal tip length of the React™ 71 Catheter were measured.	The React™ 71 Catheter met the acceptance criteria for dimensional measurements.
Tip Buckling	The React™ 71 Catheter was evaluated for the maximum compressive force it can withstand.	The React™ 71 Catheter met the acceptance criteria for tip buckling.
Kink Resistance	The React™ 71 Catheter was evaluated for the maximum kink diameter.	The React™ 71 Catheter met the acceptance criteria for kink resistance.
Particulate	The React™ 71 Catheter was evaluated per USP <788>.	The React™ 71 Catheter met the acceptance criteria for particulate.
Coating Lubricity	The React™ 71 Catheter was evaluated for the average frictional forces.	The React™ 71 Catheter met the acceptance criteria for coating lubricity.

Test	Test Method Summary	Results
Tensile Strength	The React™ 71 Catheter was evaluated per ISO 10555-1. Annex B.	The React™ 71 Catheter met the acceptance criteria for tensile strength at the hub and shaft.
Liquid Leak	The React™ 71 Catheter was evaluated per ISO 10555-1. Annex C.	The React™ 71 Catheter met the acceptance criteria for liquid leak.
Corrosion Resistance	The React™ 71 Catheter was evaluated per ISO 10555-1. Annex A.	The React™ 71 Catheter met the acceptance criteria for corrosion resistance.
Hub Aspiration Resistance	The React™ 71 Catheter was evaluated per ISO 10555-1. Annex D.	The React™ 71 Catheter met the acceptance criteria for hub air aspiration.
Radiopacity	The markerband length and wall thickness of the React™ 71 Catheter were measured. In addition, radiopacity was confirmed via fluoroscopy.	The React™ 71 Catheter met the acceptance criteria for radiopacity.
Luer Standards	The React™ 71 Catheter was evaluated per ISO 594-1 and ISO 80369-7.	The React™ 71 Catheter met the acceptance criteria for luer standards.
Torque to Failure	The React™ 71 Catheter was evaluated for transmission of proximal torque to the distal tip.	The React™ 71 Catheter was able to withstand torsional forces that are typical of clinical use.
Dynamic Pressure	The React™ 71 Catheter was evaluated for the amount of pressure it can withstand.	The React™ 71 Catheter was able to withstand pressures that are typical of clinical use.
Coating Integrity	The React™ 71 Catheter was evaluated for coating coverage and lubricity.	The React™ 71 Catheter remained coated and lubricious.

In addition, the following non-clinical bench testing was conducted to evaluate the performance of the Riptide™ Aspiration System (React™ 71 Catheter):

Test	Test Method Summary	Results
Recanalization	The Riptide™ Aspiration System (React™ 71 Catheter) was evaluated for recanalization.	The Riptide™ Aspiration System (React™ 71 Catheter) met the acceptance criteria for recanalization.
Vacuum Pressure	The Riptide™ Aspiration System (React™ 71 Catheter) was evaluated for vacuum pressure.	The Riptide™ Aspiration System (React™ 71 Catheter) met the acceptance criteria for vacuum pressure.

Test	Test Method Summary	Results
Suction Flow Rate	The Riptide™ Aspiration System (React™ 71 Catheter) was evaluated for suction flow rate.	The Riptide™ Aspiration System (React™ 71 Catheter) met the acceptance criteria for suction flow rate.
Lumen Collapse	The Riptide™ Aspiration System (React™ 71 Catheter) was evaluated for lumen collapse.	The Riptide™ Aspiration System (React™ 71 Catheter) remained patent.
Usability	The Riptide™ Aspiration System (React™ 71 Catheter) and the Penumbra System® (ACE 68 Reperfusion Catheter) were evaluated for maneuverability, flexibility, the ability to engage and apply aspiration, and the ability to safely retrieve clot.	The Riptide™ Aspiration System (React™ 71 Catheter) met the acceptance criteria for usability.

Performance Data – Animal:
Non-clinical animal testing was conducted to evaluate the safety, efficacy, and usability of the Riptide™ Aspiration System (React™ 71 Catheter) in comparison to the Penumbra System® (ACE 68 Reperfusion Catheter) at acute and chronic time points in a porcine model, both in the presence and absence of simulated clot. Non-clinical animal testing was conducted in accordance with 21 CFR Part 58 for Good Laboratory Practice (GLP) for Non-Clinical Laboratory Studies.

Performance Data – Clinical:
Not Applicable. A determination of substantial equivalence is based upon successful completion of non-clinical bench and animal testing.

Conclusion:
The design modifications incorporated do not alter the fundamental scientific technology or intended use.

Non-clinical bench and animal testing supports a determination that the subject Riptide™ Aspiration System (React™ 71 Catheter) is substantially equivalent to the predicate Penumbra System® (ACE 68 Reperfusion Catheter).