October 29, 2024

Micro Therapeutics, Inc. d/b/a ev3 Neurovascular
Tony Rizzardi
Principal Regulatory Affairs Specialist
9775 Toledo Way
Irvine, California 92618

Re: K243080
Trade/Device Name: Riptide Aspiration System
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous Catheter
Regulatory Class: Class II
Product Code: NRY
Dated: September 27, 2024
Received: September 30, 2024

Dear Tony Rizzardi:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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 -S

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
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Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K243080

Device Name
Riptide™ Aspiration System

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 thrombolytic drug therapy or who failed thrombolytic drug 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 - K243080

510(k) Owner	Micro Therapeutics, Inc. d/b/a ev3 Neurovascular 9775 Toledo Way Irvine, CA 92618, USA Establishment Registration: 2029214
Contact Person	Tony Rizzardi Principal Regulatory Affairs Specialist Telephone: (763) 505-3017 Email: tony.rizzardi@medtronic.com

Date Summary Prepared	29 October 2024
Trade Name of Device	Riptide™ Aspiration System
Common Name of Device	Catheter, Thrombus Retriever
Review Panel	Neurology
Medical Specialty	Cardiovascular
Product Code	NRY
Regulation Number	21 CFR 870.1250
Regulation Name	Percutaneous Catheter
Device Classification	Class II
Predicate Device	Riptide™ Aspiration System (K201689)

Device Description

The Riptide™ Aspiration System is designed to restore blood flow in 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, using continuous aspiration. The Riptide™ Aspiration System is composed of the following components and illustrated in **Figure 1**:

1. React™ 68 Catheter (REACT-68), React™ 71 Catheter (REACT-71, REACT-71-115, REACT-71-125)
2. Riptide™ Large Bore Aspiration Tubing (MAT-110-110)
3. Riptide™ Aspiration Pump (MAP-1000)
4. Riptide™ Collection Canister with Intermediate Tubing (MAC-1200)

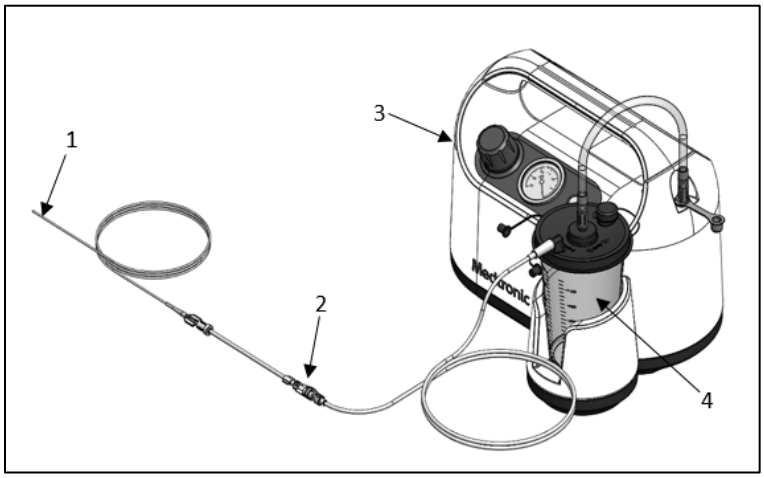

Figure 1. Riptide™ Aspiration System

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 thrombolytic drug therapy or who failed thrombolytic drug therapy are candidates for treatment.

Comparison of Technological Characteristics

Attribute	**Predicate Device:** Riptide™ Aspiration System (K201689)	**Subject Device:** Riptide™ Aspiration System (K243080)
General		
Indication for Use Statement	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.	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 thrombolytic drug therapy or who failed thrombolytic drug therapy are candidates for treatment.
Devices Comprising the System	• React™ 68 Catheter (REACT-68) • React™ 71 Catheter (REACT-71) • Riptide™ Large Bore Aspiration Tubing (MAT-110-110) • Riptide™ Aspiration Pump (MAP- 1000) • Riptide™ Collection Canister with Intermediate Tubing (MAC-1200)	• React™ 68 Catheter (REACT-68) • React™ 71 Catheter (REACT-71, REACT-71-115, REACT-71-125) • Riptide™ Large Bore Aspiration Tubing (MAT-110-110) • Riptide™ Aspiration Pump (MAP- 1000) • Riptide™ Collection Canister with Intermediate Tubing (MAC-1200)
React™ 68 Catheter		
Materials of Construction	Commonly used medical grade plastics and metals with hydrophilic coating	Same as K201689
Inner Diameter	0.068”	Same as K201689
Outer Diameter	0.083”	Same as K201689
Usable Length	132 cm	Same as K201689
Accessory	Peelable split-y introducer sheath	Same as K201689
Packaging	Polyethylene hoop/backing card, nylon-Tyvek™ pouch, SBS carton	Same as K201689
Sterilization	Ethylene oxide, SAL 10^{-6}	Same as K201689
Shelf Life	2 years	Same as K201689
React™ 71 Catheter		

Attribute	Predicate Device: Riptide™ Aspiration System (K201689)	Subject Device: Riptide™ Aspiration System (K243080)
Materials of Construction	Commonly used medical grade plastics and metals with hydrophilic coating	Same as K201689
Inner Diameter	0.071"	Same as K201689
Outer Diameter	0.0855" (Max)	Same as K201689
Usable Length	132 cm	115, 125, and 132 cm
Accessory	Peelable split-y introducer sheath	Same as K201689
Packaging	Polyethylene hoop/backing card, nylon-Tyvek™ pouch, SBS carton	Same as K201689
Sterilization	Ethylene oxide, SAL 10^{-6}	Same as K201689
Shelf Life	2 years	Same as K201689
Riptide™ Large Bore Aspiration Tubing		
Materials of Construction	Commonly used medical grade plastics	Same as K201689
Inner Diameter	0.110"	Same as K201689
Outer Diameter	0.188"	Same as K201689
Usable Length	112.0"	Same as K201689
Packaging	Nylon-Tyvek™ pouch, SBS carton	Same as K201689
Sterilization	Ethylene oxide, SAL 10^{-6}	Same as K201689
Shelf Life	3 years	Same as K201689
Riptide™ Aspiration Pump		
Vacuum Range	0-29 inHg (0-98.2 kPa)	Same as K201689
Flow Rate	MAP-1000 (60 Hz): 0-0.8 SCFM (0-23 LPM)	Same as K201689
Voltage	MAP-1000: 110-115 Vac (US)	Same as K201689
Frequency	60 Hz	Same as K201689
Duty Cycle	Non-continuous 97% (58.2 minutes on, 1.8 minutes off)	Same as K201689
Applied Part Classification	Type BF	Type CF
IEC 60601-1 and IEC 60601-1-2 Compliance	Yes: IEC 60601-1 (Edition 3.1) and IEC 60601-1-2 (Edition 4.0)	Yes: IEC 60601-1 (Edition 3.2 2020-08) IEC 60601-1-2 (Edition 4.1 2020-09)
ISO 10079-1 and ISO 10079-4 Compliance	No	Yes: ISO 10079-1 (Fourth edition 2022-03) ISO 10079-4 (First edition 2021-08)
Physical Dimensions	Length: 16.1" Depth: 13.2" Height: 12.3"	Same as K201689
Weight	MAP-1000: Approximately 24 lbs (11 kg)	Same as K201689
Noise	60.5 dBa	<70 dBa

Attribute	Predicate Device: Riptide™ Aspiration System (K201689)	Subject Device: Riptide™ Aspiration System (K243080)
Internal Components	Commonly used electrical components, fittings, and tubing.	Same as K201689
Sterilization	Non-sterile	Same as K201689
Operating Life	500 hours	Same as K201689
Riptide™ Collection Canister with Intermediate Tubing		
Materials of Construction	Commonly used medical grade plastics	Same as K201689
Volume	1200 mL	Same as K201689
Shelf Life	3 years	Same as K201689

Biocompatibility

There is no impact to the biocompatibility of the Riptide™ Aspiration System associated with the changes subject to K243080.

Performance Data – Bench

The following non-clinical bench tests were conducted for the Riptide™ Aspiration System:

Test	Test Method Summary	Results
Riptide™ Aspiration Pump		
Electrical Safety (IEC 60601-1)	Electrical safety testing conducted per IEC 60601-1 Edition 3.2 2020-08.	Pass
Electromagnetic Compatibility (IEC 60601-1-2)	Electromagnetic compatibility (EMC) testing conducted per IEC 60601-1-2 Edition 4.1 2020-09.	Pass
Riptide™ Aspiration Pump and Riptide™ Collection Canister with Intermediate Tubing		
Medical Suction Equipment (ISO 10079-1/10079-4)	Medical suction equipment testing conducted per ISO 10079-1 Fourth Edition 2022-03 and ISO 10079-4 First Edition 2021-08.	Pass
React™ 71 Catheter		
Design Validation (The length of the subject device shall be compatible with minimum length 136 cm guide catheter)	The subject device was evaluated per FDA guidance "Applying Human Factors and Usability Engineering to Medical Devices, Guidance for Industry and Food and Drug Administration Staff" (February 2016) and per FDA recognized consensus standards ISO 14971 (Third Edition 2019-12) and IEC 62366-1 (Edition 1.1 2020-06 CONSOLIDATED VERSION).	Pass
Design Validation (The subject device should be able to navigate to the distal M1 segment of the MCA over a microcatheter)	The subject device was evaluated per FDA guidance "Applying Human Factors and Usability Engineering to Medical Devices, Guidance for Industry and Food and Drug Administration Staff" (February 2016) and per FDA recognized consensus standards ISO 14971 (Third Edition 2019-12) and IEC 62366-1 (Edition 1.1 2020-06 CONSOLIDATED VERSION).	Pass

Performance Data – Animal

The determination of substantial equivalence is based upon non-clinical bench testing as there is no change to the intended use, fundamental scientific technology, or materials of construction.

Performance Data – Clinical

The determination of substantial equivalence is based upon non-clinical bench testing as there is no change to the intended use, fundamental scientific technology, or materials of construction.

Conclusion

There is no change to the intended use, fundamental scientific technology, principle of operation, and materials of construction of the subject Riptide™ Aspiration System in comparison to the legally marketed predicate Riptide™ Aspiration System (K201689). The design and labeling changes for Type CF applied part classification, meeting latest electrical safety and medical suction equipment standards (including IEC 60601-1, IEC 60601-1-2, ISO 10079-1, and ISO 10079-4), and addition of shorter length sizes of the React™ 71 Catheter (REACT-71-115 & REACT-71-125) to the system do not raise new questions of safety and effectiveness and have been tested through non-clinical bench testing using established scientific methods. The information provided in this submission supports a determination of substantial equivalence for the subject Riptide™ Aspiration System.