Micro Therapeutics, Inc. d/b/a ev3 Neurovascular
Kristy Ann Darling, RAC
Senior Regulatory Affairs Specialist
9775 Toledo Way
Irvine, CA 92618

July 21, 2020

Re: K201689
Trade/Device Name: Riptide Aspiration System
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous Catheter
Regulatory Class: Class II
Product Code: NRY
Dated: June 19, 2020
Received: June 22, 2020

Dear Kristy Ann Darling:

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 (Acting)
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)*
K201689

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 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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(k) Summary:

510(k) Owner:	Micro Therapeutics, Inc. d/b/a ev3 Neurovascular 9775 Toledo Way Irvine, CA 92618 Establishment Registration: 2029214
Contact Person:	Kristy Ann Darling Senior Regulatory Affairs Specialist Telephone: (949) 490-3819 Email: kristyann.d.darling@medtronic.com

Date Summary Prepared:	July 20, 2020
Trade Name of Device:	Riptide™ Aspiration System
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:	Riptide™ Aspiration System 510(k): K172448

Device Description:

The Riptide™ Aspiration System is composed of the following components:

1. React™ Catheters
2. Riptide™ Large Bore Aspiration Tubing
3. Riptide™ Aspiration Pump
4. Riptide™ Collection Canister with Intermediate Tubing

No changes were made to the catheters, tubing or collection canister with intermediate tubing cleared in the predicate system under K172448 and, most recently, under K183185.

The Riptide™ Aspiration Pump is designed to generate vacuum for the Riptide Aspiration System. The vacuum pressure of the Riptide Aspiration Pump is set by turning the vacuum control valve until the vacuum gauge reads a minimum of 20inHg but not exceeding 25inHg. The Riptide Aspiration Pump is reusable, non-sterile, and intended to be utilized outside of the sterile environment.

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.

Device Comparison:

Attribute	Predicate Device: Riptide™ Aspiration System (K172448)	Subject Device: Riptide™ Aspiration System
Indication for Use (IFU) 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.	Same
IEC 60601-1 Compliance	Yes	Same
IEC 60601-1-2 Compliance	Yes	Same
Voltage	110-115 Vac	220-240 Vac
Frequency	60 Hz	50/60 Hz
Sterilization	Non-sterile	Same

The following non-clinical bench testing was performed for the Riptide™ Aspiration System:

Test	Test Method Summary	Results
Functionality	The subject Riptide™ Aspiration System was tested to ensure the device meets the product specification for functionality testing.	The subject Riptide™ Aspiration System met the acceptance criteria for functional testing.
Vacuum Pressure	The subject Riptide™ Aspiration System was tested to ensure the device meets the product specification for vacuum pressure.	The subject Riptide™ Aspiration System met the acceptance criteria for maximum vacuum pressure.
Flow Rate	The subject Riptide™ Aspiration System was tested to ensure the device meets the product specification for volumetric flow rate.	The subject Riptide™ Aspiration System met the acceptance criteria for volumetric flow rate.
Electrical Safety per IEC 60601-1	The subject Riptide™ Aspiration System was tested to demonstrate it conforms to AAMI/IEC 60601-1:2005 + AMD 1:2012 Medical electrical equipment – Part 1: General requirements for basic safety and essential performance.	The subject Riptide™ Aspiration System met the acceptance criteria for demonstrating conformance to AAMI/IEC 60601-1:2005 + AMD 1:2012.
Electromagnetic Compatibility per IEC 60601-1-2	The subject Riptide Aspiration System was tested to demonstrate compliance to IEC 60601-1-2: 2014 Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance –Collateral Standard: Electromagnetic disturbances – Requirements and tests.	The subject Riptide™ Aspiration System met the acceptance criteria. for demonstrating compliance to IEC 60601-1-2.

The following non-clinical bench testing was also performed for the Riptide™ Aspiration System:

Test	Test Method Summary	Results
Recanalization	The subject Riptide™ Aspiration System was tested to ensure it is able to aspirate a clot in the occluded vessel at recanalization rates similar to the predicate device.	The subject Riptide™ Aspiration System met the acceptance criteria for recanalization for the Riptide™ Aspiration System.
Vacuum Pressure	The subject Riptide™ Aspiration System was tested to ensure it is capable of accurately translating vacuum pressure, generated by the pump, to the tip of the catheter	The subject Riptide™ Aspiration System met the acceptance criteria for vacuum pressure.
Volumetric Flow Rate	The subject Riptide™ Aspiration System was tested to ensure it generates sufficient flow through the catheter to facilitate efficacious withdrawal of the clot from the vasculature.	The subject Riptide™ Aspiration System met the acceptance criteria for volumetric flow rate.

The following non-clinical bench testing was leveraged from the predicate Riptide™ Aspiration System:

Test	Test Method Summary	Results
Functionality, Post-Durability	Leveraged from predicate device.	The subject Riptide™ Aspiration System met the acceptance criteria for functionality, post-durability.
Tip-over Resistance / Degree of Tilt	Leveraged from predicate device.	The subject Riptide™ Aspiration System met the acceptance criteria for tip-over resistance/degree of tilt.
Usability	Leveraged from predicate device.	The subject Riptide™ Aspiration System met the acceptance criteria for usability.
Clot Engagement and Aspiration	Leveraged from predicate device.	The subject Riptide™ Aspiration System met the acceptance criteria for clot engagement and aspiration.

Performance Data – Animal:

There is no change to the Indication for Use (IFU) Statement of the subject Riptide™ Aspiration System in comparison to the legally marketed predicate device. The difference in technological characteristics do not raise questions of safety and effectiveness as demonstrated through non-clinical bench testing using well-established acceptable scientific methods.

Performance Data – Clinical:

There is no change to the Indication for Use (IFU) Statement of the subject Riptide™ Aspiration System in comparison to the legally marketed predicate device. The difference in technological characteristics do not raise questions of safety and effectiveness as demonstrated through non-clinical bench testing using well-established acceptable scientific methods.

Conclusion:

There is no change to the Indication for Use (IFU) Statement of the subject Riptide™ Aspiration System in comparison to the legally marketed predicate device. In addition, the subject Riptide™ Aspiration System is equivalent in terms of fundamental scientific technology in comparison to the legally marketed predicate device. The difference in technological characteristics does not raise new questions on the safety and effectiveness as demonstrated through non-clinical bench testing using well-established acceptable scientific methods. Therefore, the subject Riptide™ Aspiration System does not raise new questions of safety or efficacy based on comparison to the legally marketed predicate device. In conclusion, the results of the nonclinical testing performed and leveraged for the subject device support a determination of substantial equivalence by demonstrating that the device is at least as safe and effective as the legally marketed predicate device.