December 2, 2024

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

Re: K243418
Trade/Device Name: Riptide™ Aspiration Pump; Riptide™ Collection Canister with Intermediate Tubing
Regulation Number: 21 CFR 878.4780
Regulation Name: Powered Suction Pump
Regulatory Class: Class II
Product Code: JCX
Dated: November 1, 2024
Received: November 4, 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,

Long H. Chen -S

Digitally signed by Long H. Chen -S
Date: 2024.12.02 09:42:22 -05'00'

Long Chen, Ph.D.
Assistant Director
DHT4A: Division of General Surgery Devices
OHT4: Office of Surgical and
Infection Control 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: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K243418

Device Name

Riptide™ Aspiration Pump;
Riptide™ Collection Canister with Intermediate Tubing

Indications for Use *(Describe)*

The Riptide™ Aspiration Pump is intended as a vacuum source for Medtronic aspiration devices or systems for use in hospitals or clinics. Refer to the Instructions for Use included with the accessory aspiration device for indications related to the procedure for which this device will be used.

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, USA Establishment Registration: 2029214
Contact Person	Tony Rizzardi Principal Regulatory Affairs Specialist Telephone: (763) 505-3017 Email: tony.rizzardi@medtronic.com

Date Summary Prepared	31 October 2024
Trade Name of Device	Riptide™ Aspiration Pump
Common Name of Device	Apparatus, suction, ward use, portable, ac-powered
Review Panel	General & Plastic Surgery
Medical Specialty	General & Plastic Surgery
Product Code	JCX
Regulation Number	21 CFR 878.4780
Regulation Name	Apparatus, suction, ward use, portable, ac-powered
Device Classification	Class II
Predicate Device	Penumbra Pump MAX™ (K122756)
Reference Device	Riptide™ Aspiration System (K172448)

Device Description

Riptide™ Aspiration Pump

The Riptide™ Aspiration Pump is an externally powered electromechanical device capable of generating a vacuum designed for drawing fluids and thrombus into the Riptide™ Collection Canister during interventional procedures. It is intended for general suction use in hospitals or clinics and is not intended for transport or field applications. The Riptide™ Aspiration Pump includes a receptacle that holds the Riptide™ Collection Canister with Intermediate Tubing in place. The intermediate tubing is connected to the vacuum inlet port.

The Riptide™ Aspiration Pump package includes the following:

- Riptide™ Aspiration Pump (LMT-RAP)
- Region specific power cord for connection to earthed receptacle.
- Riptide™ Aspiration Pump User's Manual

The following item is required for use with Riptide™ Aspiration Pump (packaged separately):

- Riptide™ Collection Canister with Intermediate Tubing (LMT-RCT)

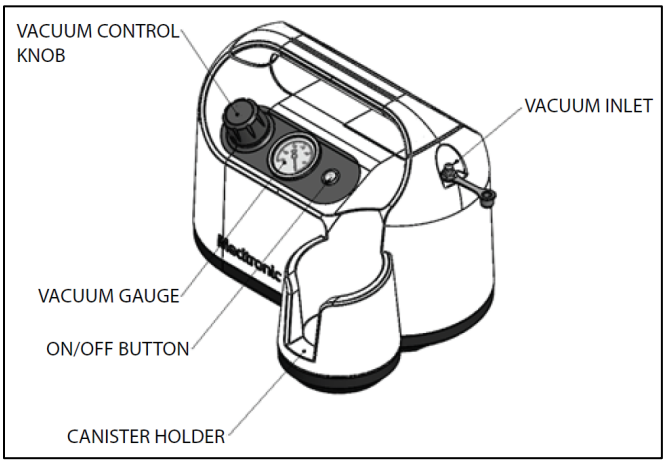

Figure 1. Riptide™ Aspiration Pump (Front)

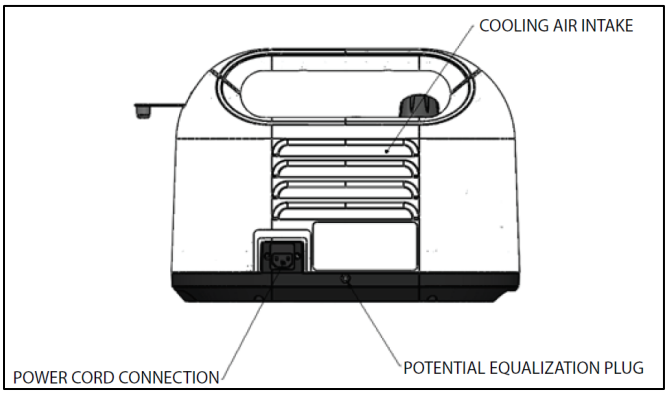

Figure 2. Riptide™ Aspiration Pump (Back)

Riptide™ Collection Canister with Intermediate Tubing

The Riptide™ Collection Canister is provided non-sterile and is pre-assembled with the Intermediate Tubing. The Riptide™ Collection Canister with Intermediate Tubing is single use. The Riptide™ Collection Canister is the repository for aspirated material. The Riptide™ Collection Canister is placed into the receptacle of the Riptide™ Aspiration Pump as shown in **Figure 3**. The Intermediate Tubing is then connected to the vacuum inlet port.

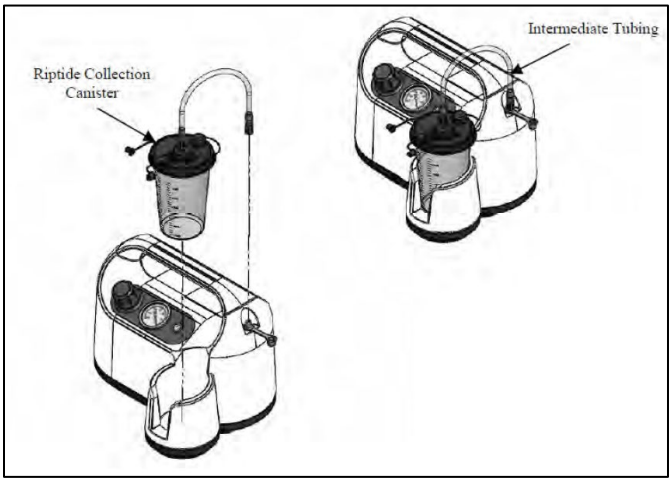

Figure 3. Riptide™ Collection Canister with Intermediate Tubing

Indications for Use

The Riptide™ Aspiration Pump is intended as a vacuum source for Medtronic aspiration devices or systems for use in hospitals or clinics. Refer to the Instructions for Use included with the accessory aspiration device for indications related to the procedure for which this device will be used.

Comparison of Technological Characteristics

Attribute	**Predicate Device:** Penumbra Pump MAX™ (PMX110 - K122756)	**Reference Device:** Riptide™ Aspiration System (MAP-1000 - K172448)	**Subject Device:** Riptide™ Aspiration Pump (LMT-RAP)
General			
Product Code/ Regulation	JCX (21 CFR 878.4780)	NRY (21 CFR 870.1250)	Same as Predicate (K122756)
Classification	Class II	Class II	Same as Predicate (K122756)
Components Comprising the System	Pump, collection canister with filter, intermediate tubing	Pump, collection canister with filter, intermediate tubing	Same as Predicate (K122756)
Pump User Manual Characteristics			
Indications for Use	The Penumbra Pump MAX™ is intended for general suction use in hospitals or clinics.	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 Pump is intended as a vacuum source for Medtronic aspiration devices or systems for use in hospitals or clinics. Refer to the Instructions for Use included with the accessory aspiration device for indications related to the procedure for which this device will be used.
User Manual	User manual with safety information and directions for the Penumbra Pump MAX™ for general suction use.	User manual with safety information and directions for the Riptide™ Aspiration Pump for neurovascular use.	User manual with safety information and directions for the Riptide™ Aspiration Pump for general suction use.
Pump Characteristics			
Vacuum Range	0-29 inHg	Same as Predicate (K122756)	Same as Predicate (K122756)
Flow Rate	60 Hz (US): 0-0.8 SCFM (0-23 LPM)	Same as Predicate (K122756)	Same as Predicate (K122756)
Voltage	100-115 Vac	110-115 Vac	110-115 Vac
Frequency	60 Hz (US)	Same as Predicate (K122756)	Same as Predicate (K122756)
Duty Cycle	Non-continuous 97.8% (45 minutes on, 1 minute off)	Non-continuous 97% (58.2 minutes on, 1.8 minutes off)	Non-continuous 97% (58.2 minutes on, 1.8 minutes off)
Applied Part Classification	Type CF	Type BF	Same as Predicate (K122756)
IEC 60601-1 and IEC 60601-1-2 Compliance	Yes: IEC 60601-1 and IEC 60601-1-2	Yes: IEC 60601-1 (Edition 3.1) and IEC 60601-1-2 (Edition 4.0)	Yes: IEC 60601-1 (Edition 3.2 2020-08) and IEC 60601-1-2 (Edition 4.1 2020-09)

Attribute	**Predicate Device:** Penumbra Pump MAX™ (PMX110 - K122756)	**Reference Device:** Riptide™ Aspiration System (MAP-1000 - K172448)	**Subject Device:** Riptide™ Aspiration Pump (LMT-RAP)
			Design changes to meet IEC 60601-1 (Edition 3.2 2020-08) compared to the Reference Device required displaying dual scale units for pressure as inHg and kPa and included addition of a new component: • Vacuum gauge (P/N 140643-01)
ISO 10079-1 and ISO 10079-4 Compliance	Yes: EN ISO 10079-1	No	Yes: ISO 10079-1 (Fourth edition 2022-03) and ISO 10079-4 (First edition 2021-08) Design changes to meet IP22 ingress protection requirement of ISO 10079-1 (Fourth edition 2022-03) required addition of new components including: • Sealing washer (P/N 12130-0003) for pressure regulator • Silicon seal (P/N 12130-0001) under power button • Silicon seal inside (P/N 12130-0002) • O-ring (P/N 12130-0004) to aid in sealing around gauge • SS plate (P/N 05131-0001) to stop plastic deformation from point loading at clamp and apply even pressure to seal and O-ring • Ring clamp (P/N 08130-0001) • Epoxy (P/N 140518-01) applied to seal handle screws (existing component) to improve sealing around interfaces
Physical Dimensions	Length: 15.5” Depth: 11.2” Height: 13.2”	Length: 16.1” Depth: 13.2” Height: 12.3”	Length: 16.1” Depth: 13.2” Height: 12.3”
Weight	22.3 lbs (10.1 kg)	Approximately 24 lbs (11 kg)	Approximately 24 lbs (11 kg)
Noise	<60 dBa	60.5 dBa	<70 dBa
Internal Components	Commonly used electrical components, fittings, and tubing.	Same as Predicate (K122756)	Same as Predicate (K122756)
Sterilization	Non-sterile	Same as Predicate (K122756)	Same as Predicate (K122756)
Operating Life	500 hours	Same as Predicate (K122756)	Same as Predicate (K122756)

Attribute	Predicate Device: Penumbra Pump MAX™ (PMX110 - K122756)	Reference Device: Riptide™ Aspiration System (MAP-1000 - K172448)	Subject Device: Riptide™ Aspiration Pump (LMT-RAP)
Collection Canister with Intermediate Tubing Characteristics			
Materials of Construction	Commonly used medical grade plastics	Same as Predicate (K122756)	Same as Predicate (K122756)
Volume	1000 mL	1200 mL	1200 mL
Shelf Life	Unknown	3 years	3 years

Biocompatibility

There is no impact to the biocompatibility of the Riptide™ Aspiration Pump associated with the proposed changes.

Performance Data – Bench

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

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
User Manual Design Validation (for general suction use)	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 ANSI/AAMI HE75:2009/(R)2018 Human Factors Engineering – Design of Medical Devices.	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

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 Pump (LMT-RAP) in comparison to the legally marketed predicate Penumbra Pump MAX™ (K122756). 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 updated indications for general use in hospitals or clinics under product code JCX do not raise different 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 Pump.