



June 13, 2025

MicroVention
Alick Tan
Associate Principal, Regulatory Affairs
35 Enterprise
Aliso Viejo, California 92656

Re: K243638

Trade/Device Name: MV Flow Aspiration Pump (MVFLOWPMP01)
Regulation Number: 21 CFR 878.4780
Regulation Name: Powered suction pump
Regulatory Class: Class II
Product Code: JCX, BTA
Dated: May 16, 2025
Received: May 16, 2025

Dear Alick Tan:

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,

James H. Digitally signed by
James H. Jang -S
Jang -S Date: 2025.06.13
14:17:52 -04'00'

James Jang, Ph.D.
Acting 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

Indications for Use

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.

K243638

?

Please provide the device trade name(s).

?

MV Flow Aspiration Pump (MVFLOWPMP01)

Please provide your Indications for Use below.

?

The MV Flow Aspiration Pump is intended for general suction use in hospitals or clinics.

Please select the types of uses (select one or both, as applicable).

- Prescription Use (Part 21 CFR 801 Subpart D)
 Over-The-Counter Use (21 CFR 801 Subpart C)

?

Contact Details

[21 CFR 807.92\(a\)\(1\)](#)

| | |
|-----------------------------|--|
| Applicant Name | MicroVention |
| Applicant Address | 35 Enterprise Aliso Viejo CA 92656 United States |
| Applicant Contact Telephone | 949-615-2603 |
| Applicant Contact | Dr. Alick Tan |
| Applicant Contact Email | alick.tan@microvention.com |

Device Name

[21 CFR 807.92\(a\)\(2\)](#)

| | |
|---------------------|--|
| Device Trade Name | MV Flow Aspiration Pump (MVFLOWPMP01) |
| Common Name | Powered suction pump |
| Classification Name | Apparatus, Suction, Ward Use, Portable, Ac-Powered |
| Regulation Number | 878.4780 |
| Product Code(s) | JCX, BTA |

Legally Marketed Predicate Devices

[21 CFR 807.92\(a\)\(3\)](#)

| Predicate # | Predicate Trade Name (Primary Predicate is listed first) | Product Code |
|-------------|--|--------------|
| K122756 | Penumbra Pump MAX | JCX |

Device Description Summary

[21 CFR 807.92\(a\)\(4\)](#)

The MV Flow Aspiration Pump is an electrically powered (100 VAC/50 Hz, 240 VAC/60 Hz) device designed to generate vacuum pressure and serve as the vacuum source intended for general suction use in hospitals or clinics. The MV Flow Aspiration Pump is not intended for use in transport or field settings.

The pump delivers 29 inHg of maximum vacuum pressure with a maximum flow rate of 36 L/min. The power button and vacuum-relief button provide pressure control. The brushless DC, dual-diaphragm pump design includes reverse-flow protection. Compatible pump accessories, supplied separately, include the MV Flow Canister.

The MV Flow Canister consists of a single-use collection canister with integrated bacteria filter, overflow protection, and a pre-installed intermediate tubing.

Intended Use/Indications for Use

[21 CFR 807.92\(a\)\(5\)](#)

The MV Flow Aspiration Pump is intended for general suction use in hospitals or clinics.

Indications for Use Comparison

[21 CFR 807.92\(a\)\(5\)](#)

The indications for use are identical.

Subject Device: The MV Flow Aspiration Pump is intended for general suction use in hospitals or clinics.

Predicate Device: The Penumbra Pump MAX is intended for general suction use in hospitals or clinics.

Technological Comparison

[21 CFR 807.92\(a\)\(6\)](#)

Per 21 CFR 807.92(a)(6), the subject device shares the same technological characteristics with the predicate device including design, principle of operation, energy source, and performance specifications. Both devices are AC-powered diaphragm pumps that provide a maximum vacuum of 29 inHg. The pumps are reusable, provided non-sterile. The single-use pump canisters accommodate up to 1000 mL of volume.

Non-Clinical and/or Clinical Tests Summary & Conclusions

[21 CFR 807.92\(b\)](#)

Nonclinical tests include performance testing per currently recognized FDA consensus standards for electrical safety (IEC 60601-1), EMC/EMI compliance (IEC 60601-1-2), device-specific pump standards (ISO 10079-1 and ISO 10079-4), and FDA Guidance Document for Powered Suction Pump 510(k). Comparative testing was conducted to compare the performance of the subject device versus legally marketed devices.

Bench testing demonstrated the device met specification, including electrical requirements, physical dimensions, maximum vacuum pressure and flow rate, and canister performance. Operational-life testing showed the device continues to meet these specifications after 500 hours of use.

The nonclinical tests support the substantial equivalence of technological characteristics between the subject and predicate devices.

No applicable clinical tests were referenced in the 510(k) to determine substantial equivalence per 21 CFR 807.92(b)(2).

Per 21 CFR 807.92(b)(3), the subject device MV Flow Aspiration Pump passed all requirements for electrical safety and device performance. The subject device shares the same or similar technological characteristics with the predicate device Penumbra Pump MAX (K122756) to establish substantial equivalence. A benefit-risk assessment was performed to compare maximum vacuum pressure, regulated vacuum pressures, free air flow rate, and fluid flow rate. This assessment determined the clinical benefits outweighed risks. Any further differences between the subject and predicate devices do not raise different questions of safety and effectiveness. The nonclinical tests demonstrate that the subject device is as safe, as effective, and performs as well as the predicate device.