July 14, 2025

Expanse Medical Inc.
Shiva Ardakani
Sr. VP QA/RA/CA
7060 Koll Canter Parkway
Suite 300
Pleasanton, California 94566

Re: K251488
Trade/Device Name: FLOWRUNNER Aspiration System
Regulation Number: 21 CFR 870.5150
Regulation Name: Embolectomy Catheter
Regulatory Class: Class II
Product Code: QEZ, KRA
Dated: June 18, 2025
Received: June 18, 2025

Dear Shiva Ardakani:

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,

GREGORY W. O'CONNELL -S

Digitally signed by GREGORY W. O'CONNELL -S
Date: 2025.07.14 14:24:05 -04'00'

Gregory O'Connell
Assistant Director
DHT2C: Division of Coronary and Peripheral Intervention Devices
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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.

510(k) Number *(if known)*
K251488

Device Name
FLOWRUNNER Aspiration System

Indications for Use *(Describe)*
The Expanse FLOWRUNNER Aspiration System is indicated for the removal of fresh, soft emboli and thrombi from vessels of the peripheral arterial and venous systems.

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 (K251488)
[As required by 21 CFR 807.92(c)]

1. Submitter's Name / Contact Person

Submitter: Expanse Medical, Inc.
7060 Koll Center Parkway, Suite 300
Pleasanton, CA 94566

Contact Person: Shiva Ardakani
Sr. VP QA/RA/CA
Phone: 925-931-1300 Ext. 209

Date Prepared: May 12, 2025

2. General Information

Trade Name:	FLOWRUNNER Aspiration System
Regulation Number	21 CFR 870.5150
Common/Usual Name:	Aspiration Catheter
Classification Name:	Embolectomy Catheter
Regulatory Class:	Class II
Product Code:	QEZ and KRA

Predicate Device: ICE Aspiration System (K234073)

3. Intended Use

The Expanse FLOWRUNNER Aspiration System is indicated for the removal of fresh, soft emboli and thrombi from vessels of the peripheral arterial and venous systems.

4. Device Description

The Expanse FLOWRUNNER Aspiration System is a peripheral thrombectomy system consisting of several components:
- FLOWRUNNER Aspiration Catheter
- FLOWRUNNER Aspiration Sheath
- Vacuum Fitting
- High Flow Stopcock Connector
- Y-Connector with Hemostatic Valve
- Hand Actuator Clip

The FLOWRUNNER Aspiration System is designed for the minimally invasive removal of thrombus from the peripheral vasculature using aspiration. The system has demonstrated compatibility with standard vascular implants, including stents and filters. It is a single use, over-the-wire, catheter-based system with the ability to infuse fluid. The FLOWRUNNER Aspiration System consists of one aspiration catheter, one aspiration sheath, one vacuum

fitting, one high flow stopcock connector, one Y-connector with hemostatic valve, and a hand actuator clip.

The FLOWRUNNER Aspiration System is introduced to the site of the primary occlusion. The Aspiration Catheter is advanced through the Aspiration Sheath and targets aspiration directly to the thrombus. The Aspiration Catheter is then retracted back into the Aspiration Sheath. This process of extension and retraction of the Aspiration Catheter is then repeated to fully aspirate the clot. Suction is applied directly to the Aspiration Catheter from an external vacuum source to aspirate thrombus from an occluded vessel (maximum pressure -27.6 in Hg and minimum pressure of -8.0 in Hg).

Sterile saline flows through the Aspiration Sheath and into the Aspiration Catheter when connected proximally. No saline is injected into the patient during aspiration. The Aspiration Catheter and Sheath are visible under fluoroscopy. The hand actuator is an optional, proximal clip attached to the Aspiration Catheter to assist the user.

The FLOWRUNNER Aspiration System comes in 12F, 14F compatible diameters and 60cm, 80cm, 100cm and 120cm lengths.

5. Performance Data

Bench testing was performed to support a determination of substantial equivalence to the predicate. Results from this testing provide assurance that the subject device FLOWRUNNER has been designed and tested to assure conformance to the requirements for its intended use.

5.1 Summary of Non-Clinical Data

As required under Section 12, Part (a)(i)(3A) of the Safe Medical Device, Act of 1990, a summary of any information regarding substantial equivalence of the device FLOWRUNNER Aspiration system is in the table of comparison. In this section, list of all testing has been outlined and summary of all the testing will be presented in the relevant section of this submission.

- Design Verification (Bench-Top Testing)
  - In-Stent and IVC Filter testing
  - Thrombus Capture Testing

6. Predicate Comparison

ICE Aspiration System K234073 is the predicate device. The FLOWRUNNER Aspiration System is substantial equivalence to the ICE Aspiration System K234073. Testing FLOWRUNNER Aspiration System demonstrated compatibility with standard vascular implants, including stents and filters and does not raise any new or different questions of safety and effectiveness.

Device / Characteristic	Predicate	Subject
	Expanse Medical, Inc. ICE Aspiration System	Expanse Medical, Inc. FLOWRUNNER Aspiration System
510(k) Number	K234073	K251488
Classification	Class II, QEW and KRA	Class II, QEZ and KRA
Intended Use	Embolectomy and Thrombectomy in Peripheral vasculature.	Embolectomy and Thrombectomy in Peripheral vasculature.
Indication for Use	The Expanse ICE Aspiration System is indicated for the removal of fresh, soft emboli and thrombi from vessels of the peripheral arterial and venous systems.	The Expanse FLOWRUNNER Aspiration System is indicated for the removal of fresh, soft, emboli and thrombi from vessels of the peripheral arterial and venous systems.
Materials	Biocompatible, commonly utilized for interventional device	Same
Packaging Configuration	Individually packaged	Same
Sterilization	EO	Same
Biocompatibility	Biocompatible	Same
Shelf Life	2 years	Same

7. Substantial Equivalence Comparison and Conclusion

For substantial equivalence to the FLOWRUNNER Aspiration System a valid, predicate device ICE Aspiration System was identified. The predicate device ICE has the same intended use. Any differences in technological characteristics did not raise new questions related to safety and effectiveness. The predicate device ICE Aspiration System was 510(k) cleared since 2023, and has been actively marketed throughout that period.

A summary of the considerations is provided in substantial equivalence section of this submission.

The FLOWRUNNER Aspiration System is deemed substantially equivalent to the predicate device ICE Aspiration System in intended use, design, materials, packaging, fundamental scientific technology, manufacturing, important performance specifications, and sterilization. Performance testing demonstrated that the FLOWRUNNER Aspiration System reliably raises no new questions of safety and effectiveness. Finally, the subject device FLOWRUNNER is offered in sizes comparable to the predicate device ICE Aspiration System intended for use within the peripheral vasculature. Therefore, the FLOWRUNNER Aspiration System is considered substantially equivalent to the predicate device ICE Aspiration System.