October 26, 2026

Expanse Medical, Inc.
Shiva Ardakani
Head of Regulatory and Quality
7060 Koll Center Pkwy.
Suite 300
Pleasanton, California 95466

Re: K262864
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: August 27, 2026
Received: August 28, 2026

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.

Before making any change significantly affecting the safety or effectiveness of the device, you must submit a new premarket notification in accordance with 21 CFR 807.81. 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 Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (Preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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 Management System Regulation (QMSR) (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: 2026.10.26 10:39:41 -04'00'

Gregory O'Connell
Assistant Director
DHT2C: Division of Coronary and Peripheral Intervention Devices
OHT2: Office of Cardiovascular 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.	K262864

Please provide the device trade name(s).

FLOWRUNNER Aspiration System

Please provide your Indications for Use below.

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

Please select the types of uses.

- [x] Prescription Use (21 CFR 801 Subpart D)
- [ ] Over-The-Counter Use (21 CFR 801 Subpart C)

Please select the age group(s) for which the device(s) is to be used.

- [ ] Neonates/Newborns (Birth to < 29 days old)
- [ ] Infants (29 days old to < 2 years old)
- [ ] Children (2 years old to < 12 years old)
- [ ] Adolescents (12 years old to < 22 years old)
- [x] Adults (22 years old and greater)

510(k) Summary (K262864)

[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: 10 August 2026

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: FLOWRUNNER Aspiration System (K251488)

This submission is intended to add the FLOWRUNNER Handle (FRH) as an optional accessory to the FLOWRUNNER Aspiration System previously cleared by K234073, K251488, and K254208.

3. Indication for Use

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

The FLOWRUNNER Aspiration System is designed for the minimally invasive removal of thrombus from the peripheral vasculature using aspiration. It is a single use, over-the-wire, catheter-based system with the ability to infuse fluids. 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, one hand actuator clip and an optional FLOWRUNNER Handle (packed separately).

The FLOWRUNNER Aspiration System is a co-axial aspiration System. The Aspiration Catheter is a single lumen coiled catheter. The proximal end is attached to a luer hub, for connection to aspiration tubing leading to a vacuum source. The distal end is an atraumatic tip, with a radiopaque marker band for visualization. The Aspiration Sheath is a single lumen, coiled catheter. The proximal end is connected to a housing containing a wiper style seal and saline luer attachment. The distal end of the catheter has a hemostatic valve residing in a stainless-steel housing, with a radiopaque marker band for visualization. FLOWRUNNER is compatible with standard vascular implants including Stents and Filters.

The mechanism of action of the FLOWRUNNER Aspiration System is as follow: FLOWRUNNER Aspiration System is introduced to the site of the primary occlusion. The Aspiration Catheter is advanced through the Aspiration Sheath and out of the distal valve, to directly apply aspiration force to the thrombus. The catheter is then retracted back into the Aspiration Sheath. This reciprocating process of extension and retraction is repeated to fully aspirate the thrombus. While inside the Aspiration Sheath, saline flows from the proximal housing to the distal end of the catheter and through the Aspiration Catheter to maintain system patency. Actuation is achieved through one of two interchangeable options: a manual Hand Actuator Clip or the battery operated FLOWRUNNER Handle (FRH), both driving the same reciprocating extension/retraction cycle. Both the Aspiration Catheter and Sheath are radiopaque and visible under fluoroscopy.

The FLOWRUNNER Aspiration System comes in a family of sizes, including SP 7F, 7F, 12F, and 14F (diameters). The effective lengths include 60cm to 130cm 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 FLOWRUNNER Handle has been designed and tested to assure conformance to the requirements for its intended use.

5.1 Summary of Non-Clinical Data

In accordance with Section 12, Part (a)(i)(3)(A) of the Safe Medical Devices Act of 1990, a summary of the information supporting the substantial equivalence of the is provided in the comparison table. This section identifies all testing performed to support the addition of FLOWRUNNER Handle (FRH) as an optional accessory to the FLOWRUNNER Aspiration System. Detailed summaries and results of the testing are provided within the applicable sections of this submission.

- Design Verification (Bench-Top Testing)
    - Electrical Safety
    - EMC / EMI
    - Battery Safety
    - Human Factors
    - FRH Functional Testing
    - Operation Life (Fatigue)
    - Packaging/ Transportation/ Shelf-life
    - Visual and Dimensional

- Biocompatibility and Package Integrity Testing have been evaluated and leveraged using K234073.
- Sterilization validation was conducted to support the addition of the FLOWRUNNER Handle (FRH) to the validated sterilization cycle for the FLOWRUNNER Aspiration System.

The FRH met all established requirements.

6. Predicate Comparison

The predicate device for this submission is the FLOWRUNNER Aspiration System (K251488). The smaller sizes represent an extension of the FLOWRUNNER device family.

Device / Characteristic	Predicate	Subject	Reference
	Expanse Medical, Inc. FLOWRUNNER Aspiration System	Expanse Medical, Inc. FLOWRUNNER Aspiration System	Cleaner™ Pro Thrombectomy System, Cleaner™ Pro Aspiration Catheter with Handpiece, Cleaner™ Pro Aspiration Canister
510(k) Number	K251488	K262864	K232679
Classification	Class II, QEZ & KRA	Class II, QEZ & KRA	Class II, QEW & KRA
Intended Use	Embolectomy and Thrombectomy in Peripheral vasculature.	Same	Embolectomy Catheter Continuous Flush Catheter.
Indication for Use	The FLOWRUNNER Aspiration System is indicated for the removal of fresh, soft, emboli and thrombi from vessels of the peripheral arterial and venous systems.	Same	Indicated for the removal of fresh, soft thrombi and emboli from the vessels of the peripheral venous vasculature, and for the infusion of physician specified fluids, including thrombolytics.
Materials	Biocompatible, commonly utilized for interventional device	Same	Biocompatible, commonly utilized for interventional device
Accessory Device provided	• FLOWRUNNER Aspiration Sheath • Vacuum Fitting • High Flow Stopcock Connector	Addition of FLOWRUNNER Handle (Packaged separately)	• An Aspiration Catheter/Dilator with Handpiece and Flushing Adapter • An external vacuum

Device / Characteristic	Predicate	Subject	Reference
	Expanse Medical, Inc. FLOWRUNNER Aspiration System	Expanse Medical, Inc. FLOWRUNNER Aspiration System	Cleaner™ Pro Thrombectomy System, Cleaner™ Pro Aspiration Catheter with Handpiece, Cleaner™ Pro Aspiration Canister
	• Y-Connector with Hemostatic Valve • Hand Actuator Clip		reservoir with pump known as the Aspiration Canister
Guide Wire Compatibility	14F – 0.035” 12F – 0.035” 7F – 0.014” SP 7F – 0.014”	Same	N/A
Catheter OD	14F (4.5 mm) 12F (3.5 mm) 7F (2.4 mm) SP 7F (2.4 mm)	Same	18F
Effective Length	60-130cm	Same	115cm
Packaging Configuration	Individually packaged	Same	Individually packaged
Sterilization	EO	Same	EO
Biocompatibility	Biocompatible	Same	Biocompatible
Shelf Life	13 Months and 24 Months	Same FRH minimum of 6 months	6 months Target 36 months
IEC 60601-1-2 IEC 60601-1 Compliance	N/A	Passed	Passed

7. Substantial Equivalence Comparison

   The FLOWRUNNER Aspiration System when used with the optional FLOWRUNNER Handle (FRH) is substantially equivalent to the predicate device, the FLOWRUNNER Aspiration System (K254208), with regards to intended use, operating principle, design concept, and technological characteristics. The FRH is an optional, battery-powered alternative to the predicate's manual Hand Actuator Clip and does not change the intended use or indications for use of the FLOWRUNNER Aspiration System. The FLOWRUNNER Handle does not alter the fundamental scientific technology of the FLOWRUNNER Aspiration System.

   A detailed comparison is provided in the Substantial Equivalence section of this submission.

8. **Conclusion**:

   The FLOWRUNNER Aspiration System family, when used with the FLOWRUNNER Handle, is substantially equivalent to the predicate FLOWRUNNER Aspiration System with

respect to intended use, design, materials, packaging, fundamental scientific technology, manufacturing processes, key performance specifications, and sterilization.

Design controls and risk management activities were conducted in accordance with ISO 14971. Performance testing demonstrated that the FLOWRUNNER Aspiration System, when used with the FLOWRUNNER Handle, meets its predetermined acceptance criteria. The addition of the FLOWRUNNER Handle as an FLOWRUNNER Aspiration System accessory does not raise different questions of safety or effectiveness.

The predicate FLOWRUNNER Aspiration System has been commercially marketed following FDA clearance. Based on the information and testing provided, the FLOWRUNNER Aspiration System when used with the FLOWRUNNER Handle is substantially equivalent to the predicate FLOWRUNNER Aspiration System.