April 19, 2024

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

Re: K234073
Trade/Device Name: ICE Aspiration System
Regulation Number: 21 CFR 870.5150
Regulation Name: Embolectomy catheter
Regulatory Class: Class II
Product Code: QEW, KRA
Dated: December 21, 2023
Received: December 22, 2023

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 (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,

Gregory W. O'connell -S
Digitally signed by Gregory W. O'connell -S
Date: 2024.04.19 07:33:02 -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

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)*
K234073

Device Name
ICE Aspiration System

Indications for Use *(Describe)*
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.

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 (K234073)
[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: Dec 19, 2023

2. General Information

Trade Name:	ICE Aspiration System
Regulation Number	21 CFR 870.5150
Common/Usual Name:	Aspiration Catheter
Classification Name:	Embolectomy Catheter
Regulatory Class:	Class II
Product Code:	QEW, KRA
Predicate Device:	Indigo Aspiration System (K180939)
Reference Device:	JETi 88 Peripheral Thrombectomy System (K183403)

3. Intended 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.

4. Device Description

The Expanse ICE Aspiration System is a peripheral thrombectomy system consisting of several components:

- ICE Aspiration Catheter
- ICE Aspiration Sheath
- Vacuum Fitting
- High Flow Stopcock Connector
- Y-Connector with Hemostatic Valve
- Hand Actuator Clip

The ICE 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 fluid. The ICE 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 ICE 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.

5. Performance Data

Bench and animal testing were performed to support a determination of substantial equivalence to the predicate. Results from this testing provide assurance that the subject device 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 Devices Act of 1990, a summary of any information regarding substantial equivalence of the device follows. 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.

- Animal Study
    - Acute Performance
    - Fluid and Contrast Injection
    - Radiopacity
- Biocompatibility
- Design Verification (Bench-Top Testing)
    - External Tip and Housing Configuration
    - Air and Liquid Leak
    - Catheter Bond and Tip Bond Strength
    - Corrosion
    - Compatibility with Vacuum Pumps/ Generators
    - Compatibility with Accessories
    - Fatigue
    - Kink Resistance
    - Trackability/ Pushability and Retraction
    - Torsional Bond Strength

- Shelf Life
- Sterilization
- Packaging

The Aspiration ICE System met all established requirements.

6. Predicate Comparison

Indigo Aspiration System (predicate) and JETi 88 System (reference) were chosen due to substantial equivalence to the ICE Aspiration System. ICE Aspiration System does not raise any new or different questions of safety and effectiveness.

Device / Characteristic	Predicate	Subject	Reference
	Penumbra Inc, Indigo Aspiration System	Expanse Medical, Inc. ICE Aspiration System	Walk Vascular LLC, JETi AIO Peripheral Thrombectomy System
510(k) Number	K180939	TBD	K183403
Classification	Class II, QEW	Class II, QEW	Class II, QEZ
Intended Use	Embolectomy and Thrombectomy in Peripheral vasculature.	Embolectomy and Thrombectomy in Peripheral vasculature.	Embolectomy and Thrombectomy in Peripheral vasculature.
Indication for Use	Non-surgical removal of emboli and thrombi from vessels of the peripheral arterial and venous systems and for the injection, infusion, and/or aspiration of contrast media and other fluids into or from a blood vessel. NOT for use in the coronary or cerebral vasculature.	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.	JETi 88 Peripheral Thrombectomy System is intended to: -remove/aspirate fluid and break-up soft emboli and thrombus from the peripheral vasculature, and -subselectively infuse/deliver diagnostics or therapeutics with or without vessel occlusion.
Materials	Biocompatible, commonly utilized for interventional devices	Biocompatible, commonly utilized for interventional devices	Biocompatible, commonly utilized for interventional devices
Packaging Configuration	Individually packaged	Individually packaged	Individually packaged
Sterilization	EO	EO	EO
Shelf Life	36 months	12 Months	UNKNOWN

7. Substantial Equivalence Comparison and Conclusion

For substantial equivalence to the ICE Aspiration System a valid, predicate device was identified. The predicate device has the same intended use. Any differences in technological characteristics did not raise new questions related to safety and effectiveness. The predicate device was 510(k) cleared 5 years ago, and has been actively marketed throughout that period.

Expanse Medical has considered the following in evaluation of substantial equivalence:

- Predicate device was cleared using well established methods
- Predicate device met or exceeded expected safety and performance
- Predicate device is without unmitigated use related or design related safety issues
- Predicate device is without an associated design related recall

A summary of the considerations is provided in substantial equivalence section of this submission. The predicate device used to support this 510(k)-submission used well established methods, had low frequency of reported adverse events and a well-established safety profile through a history of safe use during its on-going marketing duration, and has no known unmitigated use-related or design related safety issues or associated design-related recalls.

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