November 20, 2024

Penumbra, Inc.
Soltanzadeh Sindokht (Sisi)
Sr. Regulatory Affairs Specialist
One Penumbra Place
Alameda, California 94502

Re: K242520
Trade/Device Name: Element Vascular Access System
Regulation Number: 21 CFR 870.1340
Regulation Name: Catheter Introducer
Regulatory Class: Class II
Product Code: DYB
Dated: August 23, 2024
Received: August 23, 2024

Dear Soltanzadeh Sindokht (Sisi):

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,

Finn E. Donaldson -S

Digitally signed by Finn E. Donaldson -S
Date: 2024.11.20 11:22:46 -05'00'

Finn Donaldson
Assistant Director (acting)
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)*
K242520

Device Name
Element Vascular Access System

Indications for Use *(Describe)*
The Element Vascular Access System is indicated for the introduction of therapeutic or diagnostic devices into the vasculature.

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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1 510(k) Summary

1.1 Sponsor/Applicant Name and Address

Penumbra, Inc.
One Penumbra Place
Alameda, CA 94502 USA

1.2 Sponsor Contact Information

Sindokht (Sisi) Soltanzadeh
Sr. Regulatory Affairs Specialist
Phone: (510) 995-9792
Email: ssoltanzadeh@penumbrainc.com

1.3 Date of Preparation of 510(k) Summary

November 20, 2024

1.4 Device Trade or Proprietary Name

Element Vascular Access System

1.5 Device Classification

Regulatory Class:	II
Classification Panel:	Cardiovascular
Classification Name:	Introducer, Catheter
Regulation Number:	21 CFR §870.1340
Product Code:	DYB

1.6 Predicate/Reference Devices

510(k) Number	Name of Device
Predicate Device	
K171999	Performer Introducer
Reference Device	
K221822	BENCHMARK BMX81 Access System

1.7 Indications for use

Subject Device: The Element Vascular Access System is indicated for the introduction of therapeutic or diagnostic devices into the vasculature.

Predicate Device: Performer™ Introducers and Guiding Sheaths are intended to introduce therapeutic or diagnostic devices into the vasculature.

Reference Device: The BENCHMARK BMX81 Access System is indicated for the introduction of interventional devices into the peripheral, coronary, and neuro vasculature.

1.8 Predicate Device:

The Performer™ Introducer is composed of an introducer sheath and dilator(s). This device may also be included in a set with a wire guide, serial dilators, a needle, and a syringe. The Performer™ Introducer is intended to facilitate the introduction of therapeutic or diagnostic devices into the vasculature. The sheath component of the device is manufactured in diameters ranging from 4-18 French (Fr) and lengths ranging from 5-85 centimeters (cm). The distal tip of the sheath may be straight or angled. The dilator component of the device is designed with an outside diameter consistent with the inside diameter of the sheath component.

1.9 Reference Device:

The BENCHMARK BMX81 Access System is a medical device system designed to provide a conduit for introduction of therapeutic devices to the peripheral, coronary, and neurovascular anatomy. This device is a three-component system comprised of the BMX81 Delivery Catheter, Penumbra (Neuron 5F) Select Catheter, and a Dilator. The BMX81 Delivery Catheter can be used individually with a 0.038 in [0.97 mm] guidewire or together with the Neuron 5F Select Catheter to access the desired anatomy. The sheath component of the device contains an inner diameter of 6 French (Fr) and lengths ranging from 55 – 115 centimeters (cm).

1.10 Comparison to Predicate and Reference Devices:

The predicate device Performer Introducer (K171999) and reference device BENCHMARK BMX81 Access System (K221822) are both similar to the subject device for use in facilitating the introduction of therapeutic or diagnostic devices into the vasculature. Both devices contain a catheter sheath and a dilator. The subject device is comparable to that of the predicate and reference device in terms of intended use, principles of operation, and basic technological characteristics. However, the subject device contains additional diameters, lengths, differing materials, and components (e.g., markerband and Tuohy valve) to the predicate device (K171999). The subject device and reference device (K221822) both have a hydrophilic coating. The substantial equivalence of the subject device modifications are supported by the performance data identified below.

1.11 Performance Data

The following performance data were provided in support of the subject device:

- Design Verification
- Biocompatibility
- Shelf-Life
- Packaging Validation
- Sterilization

The subject device met all established requirements.

1.11.1 Summary of Bench Performance Testing

The following bench performance testing was conducted on the subject device:

Test	Test Method Summary	Conclusion
Dimensional/Visual Inspection Test	Confirms units meet all dimensional and visual product specifications.	Acceptance Criteria met
Simulated Use Test	Confirms the functionality of units using a clinically relevant bench-top model.	Acceptance Criteria met
Tensile Test	Confirms units meet product specification related to tensile strength.	Acceptance Criteria met
Particulate Test	Particulates generated during simulated use were evaluated.	Acceptance Criteria met
Liquid Leakage Pressure Test	Confirms units can withstand sufficient pressure.	Acceptance Criteria met
Fluoroscopy Test	Confirms markerband is fluoroscopically visible.	Acceptance Criteria met
Friction Test	Confirms units meet product specification related to friction.	Acceptance Criteria met
Corrosion Resistance Test	Confirms there is no visible corrosion on units when tested.	Acceptance Criteria met
Elongation Test	Confirms units meet product specification related to elongation.	Acceptance Criteria met
Distal Tip Stiffness Test	Confirms units have appropriate distal tip stiffness.	Acceptance Criteria met
Flexibility Kink Resistance Test	Confirms units have appropriate flexibility kink resistance.	Acceptance Criteria met

1.11.2 Animal and Clinical Data

No animal or clinical studies were deemed necessary to support the substantial equivalence of the subject device.

1.12 Summary of Substantial Equivalence

The device testing described in the 510(k) Summary demonstrates the subject device Element Vascular Access System is substantially equivalent to the predicate device Performer Introducer in regard to intended use, operating principle, design concept, fundamental technology, and device performance.