December 11, 2024

Penumbra, Inc.
Akshay Kulkarni
Regulatory Affairs Specialist II
One Penumbra Place
Alameda, California 94502

Re: K242033
Trade/Device Name: Access25™ Delivery Microcatheter
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous Catheter
Regulatory Class: Class II
Product Code: QJP, DQY
Dated: July 10, 2024
Received: July 11, 2024

Dear Akshay Kulkarni:

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,

Michael Mcknight -S

for Naira Muradyan, Ph.D.
Assistant Director
DHT5A: Division of Neurosurgical,
Neurointerventional, and
Neurodiagnostic Devices
OHT5: Office of Neurological and
Physical Medicine 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)*
K242033

Device Name
Access25™ Delivery Microcatheter

Indications for Use *(Describe)*
The Access25 Delivery Microcatheter is indicated to assist in the delivery of diagnostic agents, such as contrast media, and therapeutic devices, such as occlusion coils, to the peripheral and neuro 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

(as required by 21 CFR 807.92)

Pursuant to Section 12, Part (a)(i)(3A) of the Safe Medical Devices Act of 1990, Penumbra, Inc. is providing the summary of Substantial Equivalence for the Access25 Delivery Microcatheter.

1.1 Sponsor/Applicant Name and Address

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

1.2 Sponsor Contact Information

Akshay Kulkarni
Regulatory Affairs Specialist II
Phone: (857) 763-9024
Email: akulkarni@penumbrainc.com

1.3 Date of Preparation of 510(k) Summary

December 09, 2024

1.4 Device Trade or Proprietary Name

Access25™ Delivery Microcatheter

1.5 Device Classification

Regulatory Class:	II
Classification Panel:	Cardiovascular
Classification Name:	Percutaneous Catheter
Regulation Number:	21 CFR §870.1250
Product Code:	QJP, DQY

1.6 Predicate Device – Lantern Delivery Microcatheter

510(k) Number	Name of Device
K152840	Lantern™ Delivery Microcatheter

1.7 Device Description

The Access25 Delivery Microcatheter (Access25) is a single lumen medical device designed to aid a physician in accessing distal vasculature when used in conjunction with a guide catheter and micro guidewire. The Access25 Delivery Microcatheter is supplied with annealed stainless steel mandrels that can be used to shape the distal tip as desired.

The Access25 Delivery Microcatheter may be available in the following shapes:

- Straight
- 45 degree
- 90 degree
- 130 degree (J)

The Access25 Delivery Microcatheter is supplied sterile for use in a sterile clinical field.

1.8 Indications for Use

The Access25 Delivery Microcatheter is indicated to assist in the delivery of diagnostic agents, such as contrast media, and therapeutic devices, such as occlusion coils, to the peripheral and neuro vasculature.

1.9 Comparison of Technological Characteristics with the Predicate Device

	Lantern Delivery Microcatheter [Predicate]	**Access25 Delivery Microcatheter [Subject]**
Classification	Class II, DQY	Class II, QJP, DQY
510(k) no.	K152840	K242033
Indication	The Lantern Delivery Microcatheter is intended to assist in the delivery of diagnostic agents, such as contrast media, and therapeutic devices, such as occlusion coils, to the peripheral and neuro vasculature.	The Access25 Delivery Microcatheter is indicated to assist in the delivery of diagnostic agents, such as contrast media, and therapeutic devices, such as occlusion coils, to the peripheral and neuro vasculature.
Dimensions		
Inner Diameter	0.025 in. min	SAME
Proximal Outer Diameter	0.040 in. max	SAME
Distal Outer Diameter	0.037 in. max	SAME
Effective Lengths	80 cm, 110 cm, 115 cm, 130 cm, 135 cm, 150 cm, 160 cm	150 cm, 160 cm, and 170 cm
Materials		
Materials	Commonly used medical grade plastics & metals	SAME
Coating	Hydrophilic (proprietary)	SAME
Attributes		
Accessories	Peelable Introducer Sheath, Shaping Mandrel, RHV	SAME
Packaging Configuration	Individual catheter in tray, or hoop attached to packaging card, pouch, and box	SAME

Packaging Materials	Polyethylene, PET, Polyester, Tyvek	SAME
Sterilization	EO	SAME
Shelf-Life	36 Months	12 Months
Use	Single use, disposable	SAME

1.10 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.

1.10.1 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	The catheter outer diameter, inner diameter, length, and coating length were measured.	Acceptance Criteria met
Simulated Use Test	Simulated use was conducted in a clinically relevant anatomical model using interventional devices.	The device performs as intended under simulated use conditions
Tensile Test	The peak tensile force was evaluated per ISO 10555-1 after preconditioning in a simulated use model.	Acceptance Criteria met
Particulate Test	Particulates generated during simulated use with clinically relevant interventional devices were evaluated.	Particulate generation was comparable to predicate device
Burst Pressure Test	Confirms units can withstand sufficient pressure per ISO 10555-1 after simulated use.	Acceptance Criteria met
Radiopacity Test	Confirms markerband(s) are fluoroscopically visible.	Acceptance Criteria met
Flow Rate Test	Confirms contrast media can be delivered through the catheter lumen.	Acceptance Criteria met
Friction Test	Confirms units meet product specification related to friction.	Friction results were comparable to the predicate
Corrosion Resistance Test	Confirms there is no visible corrosion on units when tested per ISO 10555-1.	Acceptance Criteria met

Test	Test Method Summary	Conclusion
Torque Strength Test	The device was evaluated for torque strength by measuring the number of catheter rotations until failure .	Acceptance Criteria met
Elongation Test	Confirms units meet product specification related to elongation.	Acceptance Criteria met
Hub/Air Test	Confirms units have no leaks when tested per ISO 10555-1.	Acceptance Criteria met
Distal Tip Stiffness Test	The maximum compressive force to cause catheter tip buckling was measured.	Distal tip stiffness was comparable to the predicate.
Kink Resistance Test	Confirms units have appropriate kink resistance.	Acceptance Criteria met
Liquid Leakage Test	Confirms units can withstand sufficient pressure.	Acceptance Criteria met

1.10.2 Summary of Biocompatibility Testing

The following biocompatibility testing was conducted for the subject device:

Tests	Test Method Summary	Results
Cytotoxicity: MEM Elution	Tested in accordance with ISO 10993-5	Pass: Non-cytotoxic
Sensitization: Magnusson-Kligman Method	Tested in accordance with ISO 10993-10	Pass: Non-sensitizing
Irritation: Intracutaneous Reactivity	Tested in accordance with ISO 10993-23	Pass: Non-irritating
Systemic Toxicity: Acute Systemic Injection	Tested in accordance with ISO 10993-11	Pass: Non-toxic
Systemic Toxicity: Material-Mediated Pyrogen	Tested in accordance with USP <151>	Pass: Non-pyrogenic
Hemocompatibility: Hemolysis (direct contact)	Tested in accordance with ISO 10993-4	Pass: Non-hemolytic
Hemocompatibility: Hemolysis (indirect contact)	Tested in accordance with ISO 10993-4	Pass: Non-hemolytic
Hemocompatibility: In-vitro Thrombogenicity	Tested in accordance with ISO 10993-4	Pass: Non-thrombogenic
Hemocompatibility: Complement Activation	Tested in accordance with ISO 10993-4	Pass: Non-activator of complement system
Hemocompatibility: Partial Thromboplastin Time (PTT)	Tested in accordance with ISO 10993-4	Pass: Hemocompatible

1.10.3 Sterilization

The Access25 Delivery Microcatheter is sterilized using a validated EO sterilization process in accordance with ISO 11135-1, Sterilization of Health Care Products – Ethylene Oxide –

Part 1: Requirements for Development, Validation and Routine Control of a Sterilization Process for Medical Devices.

1.10.4 Pyrogenicity

The Access25 Delivery Microcatheter has been established to be non-pyrogenic based on material mediated rabbit pyrogen biocompatibility testing per USP <151> and LAL testing per ANSI/AAMI ST72 to meet < 2.15 EU/device acceptance criteria.

1.10.5 Animal and Clinical Data

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

1.11 Summary of Substantial Equivalence

The subject Access25 Delivery Microcatheter is substantially equivalent to the predicate Lantern Delivery Microcatheter. The subject device has the identical intended use as the predicate device. The device testing described in the 510(k) Summary demonstrates the subject device is substantially equivalent to the predicate device in regard to intended use, operating principle, design concept, fundamental technology, and device performance.