June 10, 2026

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

Re: K250690
Trade/Device Name: Penumbra System (Thunderbolt Aspiration Tubing)
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous Catheter
Regulatory Class: Class II
Product Code: NRY
Dated: May 12, 2026
Received: May 13, 2026

Dear Sindokht (Sisi) Soltanzadeh:

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 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,

NAIRA MURADYAN -S

Naira Muradyan, PhD
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)*
K250690

Device Name
Penumbra System (Thunderbolt Aspiration Tubing)

Indications for Use *(Describe)*

Penumbra Reperfusion Catheters and Separators
As part of the Penumbra System, the Reperfusion Catheters and Separators are indicated for use in the revascularization of patients with acute ischemic stroke secondary to intracranial large vessel occlusive disease (within the internal carotid, middle cerebral – M1 and M2 segments, basilar, and vertebral arteries) within 8 hours of symptom onset. Patients who are ineligible for thrombolytic drug therapy or who failed thrombolytic drug therapy are candidates for treatment.

Penumbra Thunderbolt Aspiration Tubing
As part of the Penumbra System, the Penumbra Thunderbolt Aspiration Tubing is indicated to connect the Penumbra Reperfusion Catheters to the Penumbra Aspiration Pump.

Penumbra Aspiration Pump
The Penumbra Aspiration Pump is indicated as a vacuum source for Penumbra Aspiration 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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) Summary – K250690

1. Submitter

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

Contact Person:
Sindokht (Sisi) Soltanzadeh
Email: ssoltanzadeh@penumbrainc.com

Date of Preparation: June 08, 2026

2. Subject Device

Device Name:	Penumbra System (Thunderbolt Aspiration Tubing)
Regulatory Class:	Class II
Regulation Name:	Percutaneous Catheter
Regulation Number:	21 CFR 870.1250
Product Code:	NRY

3. Predicate Device

510(k) Number	Name of Device
K182522	Penumbra System (Modified 110 Aspiration Tubing)

4. Device Description

The Penumbra System is comprised of the following devices:

- Penumbra Reperfusion Catheter
- Penumbra Aspiration Pump
- Penumbra Aspiration Pump Canister/Tubing
- Penumbra Thunderbolt Aspiration Tubing
- Penumbra Separator

The Penumbra System is designed to remove thrombus from and restore blood flow to the neurovasculature using aspiration. The Reperfusion Catheter delivers aspiration from the pump directly to the site of occlusion to remove the clot. The Separator may be used to clear the lumen of the Reperfusion Catheter should it become blocked with thrombus. The Reperfusion Catheter is introduced through a guide catheter or long femoral sheath and into the intracranial vasculature and guided over a neurovascular guidewire to the site of the primary occlusion. The Penumbra Reperfusion Catheter is used with the Penumbra Aspiration Pump to aspirate thrombus from an occluded vessel. The Penumbra Reperfusion Catheter is connected to the Penumbra Aspiration Pump using the Penumbra Thunderbolt Aspiration Tubing and the Penumbra Aspiration Pump Canister.

The Penumbra Thunderbolt Aspiration Tubing facilitates the transfer of vacuum between the Penumbra Reperfusion Catheter and Penumbra Aspiration Pump while providing modulated or continuous aspiration. Modulated aspiration is provided when the Penumbra Thunderbolt Aspiration Tubing alternates between connecting the Reperfusion Catheter to the Penumbra Aspiration Pump and a sterile saline intravenous (IV) bag at ambient pressure in a predetermined modulated aspiration sequence. Vacuum is applied to the Reperfusion Catheter when connected to the Penumbra Aspiration Pump. Positive pressure is applied to the Reperfusion Catheter when connected to a sterile saline IV bag at ambient pressure. In non-clinical benchtop testing simulating complete occlusion of a Penumbra Reperfusion Catheter RED 72 during modulated aspiration, connection to a sterile saline IV bag at ambient pressure applied a positive pressure of 7.6 inHg (193 mmHg) within the occluded Reperfusion Catheter tip.

The Penumbra System Thunderbolt Aspiration Tubing is provided in a kit configuration with a Penumbra Reperfusion Catheter (RED 62, RED 68, or RED 72), along with a steam shaping mandrel, rotating hemostasis valve (RHV), peelable sheath, and optionally, SENDit Technology. The Penumbra Separator is provided with an introducer and torque device. The devices are visible under fluoroscopy. Modulated aspiration may only be used with the Penumbra Reperfusion Catheters RED 62, RED 68, and RED 72, without use of any devices within the Reperfusion Catheter (e.g., no Separator or 3D Revascularization Device).

5. Indications For Use

Penumbra Reperfusion Catheters and Separators

As part of the Penumbra System, the Reperfusion Catheters and Separators are indicated for use in the revascularization of patients with acute ischemic stroke secondary to intracranial large vessel occlusive disease (within the internal carotid, middle cerebral –

M1 and M2 segments, basilar, and vertebral arteries) within 8 hours of symptom onset. Patients who are ineligible for thrombolytic drug therapy or who failed thrombolytic drug therapy are candidates for treatment.

Penumbra Thunderbolt Aspiration Tubing

As part of the Penumbra System, the Penumbra Thunderbolt Aspiration Tubing is indicated to connect the Penumbra Reperfusion Catheters to the Penumbra Aspiration Pump.

Penumbra Aspiration Pump

The Penumbra Aspiration Pump is indicated as a vacuum source for Penumbra Aspiration Systems.

6. Comparison of Technological Characteristics with the Predicate Device

Device Attribute	Predicate Device	Subject Device
Trade Name	Penumbra System (Modified 110 Aspiration Tubing)	Penumbra System (Thunderbolt Aspiration Tubing)
Classification	Class II, NRY, 21 CFR 870.1250	SAME
510(k) Number	K182522	K250690
Indications for Use	Penumbra Reperfusion Catheters and Separators As part of the Penumbra System, the Reperfusion Catheters and Separators are indicated for use in the revascularization of patients with acute ischemic stroke secondary to intracranial large vessel occlusive disease (within the internal carotid, middle cerebral – M1 and M2 segments, basilar, and vertebral arteries) within 8 hours of symptom onset. Patients who are ineligible for intravenous tissue plasminogen activator (IV t-PA) or who fail IV t-PA therapy are candidates for treatment. Penumbra 3D Revascularization Device As part of the Penumbra System, the Penumbra 3D Revascularization Device is	Penumbra Reperfusion Catheters and Separators As part of the Penumbra System, the Reperfusion Catheters and Separators are indicated for use in the revascularization of patients with acute ischemic stroke secondary to intracranial large vessel occlusive disease (within the internal carotid, middle cerebral – M1 and M2 segments, basilar, and vertebral arteries) within 8 hours of symptom onset. Patients who are ineligible for thrombolytic drug therapy or who failed thrombolytic drug therapy are candidates for treatment. Penumbra Thunderbolt Aspiration Tubing As part of the Penumbra System, the Penumbra Thunderbolt Aspiration Tubing is indicated to

Device Attribute	Predicate Device	Subject Device
	indicated for use in the revascularization of patients with acute ischemic stroke secondary to intracranial large vessel occlusive disease (within the internal carotid, middle cerebral – M1 and M2 segments) within 8 hours of symptom onset. Patients who are ineligible for intravenous tissue plasminogen activator (IV t-PA) or who fail IV t-PA therapy are candidates for treatment. Penumbra Aspiration Tubing As part of the Penumbra System, the Penumbra Sterile Aspiration Tubing is indicated to connect the Penumbra Reperfusion Catheters to the Penumbra Aspiration Pump. Penumbra Aspiration Pump The Penumbra Aspiration Pump is indicated as a vacuum source for Penumbra Aspiration Systems.	connect the Penumbra Reperfusion Catheters to the Penumbra Aspiration Pump. Penumbra Aspiration Pump The Penumbra Aspiration Pump is indicated as a vacuum source for Penumbra Aspiration Systems.
Aspiration Mode	Continuous	Modulated and Continuous
Device Materials	Commonly used materials for interventional devices	SAME
Tubing Inner Diameter (ID)	0.110 in	0.125 in
Proximal Tubing Outer Diameter (OD)	0.188 in	0.230 in
Distal Tubing Outer Diameter (OD)	0.188 in	0.225 in
Overall Length	100 in	120 in
Packaging Materials	Commonly used materials for interventional devices	SAME

Device Attribute	Predicate Device	Subject Device
Packaging Configurations	Individual and Kit Packaged	Kit Packaged Only
Aspiration Pump	Penumbra Aspiration Pump	SAME
Condition Supplied	Sterile and Single Use	SAME
Sterilization Method	Ethylene Oxide (EO)	SAME

7. Summary of Non-Clinical Data

The following non-clinical testing data were provided in support of the substantial equivalence determination:

- Biocompatibility
- Performance Testing – Design Verification
- Shelf Life
- Packaging Validation
- Sterilization
- Good Laboratory Practice (GLP) Animal Study
- Software
- Electrical Safety/Electromagnetic Compatibility (EMC) Testing

The subject device met all established requirements.

7.1 Biocompatibility

The biocompatibility evaluation for the Thunderbolt Aspiration Tubing was conducted in accordance with ISO 10993-1, USP standards, and 21 CFR Part 58, Good Laboratory Practice (GLP). The battery of testing included the following tests:

Test	Acceptance Criteria	Conclusion
Cytotoxicity: MEM Elution	Sample extracts must have a cytotoxic reactivity score of Grade 2 or lower.	Pass Non-cytotoxic
Sensitization: Magnusson-Kligman Method	Test group shall yield Grade < 1 score on Magnusson and Kligman scale (provided control group yields Grade < 1).	Pass Non-sensitizing

Test	Acceptance Criteria	Conclusion
Irritation: Intracutaneous Toxicity	The difference between the average scores for the extract of the test article and the control must be ≤ 1.0.	Pass Non-irritating
Systemic Toxicity: Acute Systemic Injection	Sample extracts must not cause significant biological reaction greater than control. That is: • Death in 2 or more animals. • Signs of toxicity in 2 or more animals (i.e. convulsions, prostration). • Weight loss > 10% in 3 or more animals.	Pass Non-toxic
Systemic Toxicity: Material Mediated Pyrogen	Sample extracts must not cause a total rise in body temperature of ≥ 0.5 ºC.	Pass Non-pyrogenic
Hemocompatibility: Hemolysis (indirect contact)	Sample extracts must be non-hemolytic (≤ 2% hemolytic index).	Pass Non-hemolytic

Biocompatibility test results demonstrate biological safety per ISO 10993 and USP requirements.

7.2 Performance Testing – Design Verification

The following design verification tests were performed on the Thunderbolt Aspiration Tubing.

Test	Test Method Summary	Conclusion
Dimensional/Visual	Confirms the units meet all dimensional and visual product specifications.	Acceptance Criteria Met
Valve Testing	Confirms the units meet all product specifications related to valve pressurization and functionality.	Acceptance Criteria Met
Leak Testing	Confirms the units meet all product specifications related to leak resistance.	Acceptance Criteria Met
Tensile Testing	Confirms the units meet all product specifications related to tensile strength.	Acceptance Criteria Met
Simulated Use	Confirms the functionality of units using clinically relevant benchtop model.	Acceptance Criteria Met
System Compatibility	Confirms the compatibility of units with system devices and accessory components, including reperfusion catheter integrity and Luer compatibility per ISO 80369-7.	Acceptance Criteria Met
System Durability	Confirms the units meet all product specifications related to durability for the procedure duration.	Acceptance Criteria Met
Flow Rate and Catheter Tip Pressure	The flow rate and pressures within the catheter tip were measured.	Flow rate and pressures were characterized
Shelf Life	Confirms expiration date based on accelerated aging test studies.	Acceptance Criteria Met
Packaging Validation	Confirms the units meet all packaging specifications.	Acceptance Criteria Met
Sterilization	Confirms the units are sterilized in accordance with ISO 11135+A1 and ISO 10993-7.	Acceptance Criteria Met

7.3 GLP Animal Study

The safety of Thunderbolt Aspiration Tubing modulated aspiration with a Reperfusion Catheter when occlusive in porcine subclavian and lingual arteries was evaluated in accordance with the "Code of Federal Regulations of the Food and Drug Administration 21 CFR, Part 58 – Good Laboratory Practices for Nonclinical Laboratory Studies". The study evaluated Thunderbolt Aspiration Tubing modulated aspiration (with saline inflow) compared to continuous aspiration with Penumbra System 110 Aspiration Tubing as a concurrent control.

Modulated aspiration or continuous aspiration was applied continuously for five (5) minutes in each treatment vessel. Vascular response was assessed post-treatment by contrast angiography. Vascular response was also assessed at subacute and chronic timepoints by gross necropsy and histopathology of associated vasculature performed by the Study Pathologist. No significant differences were observed in vascular response angiographically or pathologically between the test and control treated vessels. The histopathological findings were considered minimal and were not considered by the Study Pathologist to be clinically relevant.

7.4 Software

Software verification and validation testing and documentation for the subject Thunderbolt Aspiration Tubing was provided as per FDA Guidance for Industry and FDA Staff, "Content of Premarket Submissions for Device Software Functions" (issued June 14, 2023).

7.5 Electrical Safety/EMC Testing

Electrical Safety and EMC testing were conducted on the subject Thunderbolt Aspiration Tubing. The subject device complies with the requirements of IEC 60601-1, IEC 60601-1-2, IEC 60601-1-6, AIM 7351731, ISO 10079-1, and ISO 10079-4.

8. Clinical Study

Summary

The Acute Ischemic Stroke Study with the Penumbra System® including Thunderbolt® Aspiration Tubing (THUNDER) was a prospective, single-arm, multicenter study designed to demonstrate the safety and effectiveness of the Penumbra System including Thunderbolt Aspiration Tubing (Thunderbolt) in a population presenting with acute ischemic stroke (AIS) secondary to intracranial large vessel occlusion (LVO) who are eligible for mechanical neurothrombectomy. The study was conducted at 29 sites in the United States.

Patient Population

Inclusion Criteria

1. Patient age 18 - 80 years.
2. Treatment within 8 hours of symptom onset.
3. Pre-stroke modified Rankin Scale (mRS) 0-2.
4. Patient experiencing acute ischemic stroke secondary to intracranial large vessel occlusion in the internal carotid, middle cerebral (M1 or M2), basilar, or vertebral artery.
5. If patient is eligible for thrombolytic therapy, it was administered as soon as possible, and no later than 3 hours from stroke symptom onset.
6. Planned frontline treatment with Penumbra System including Thunderbolt modulated aspiration.
7. Informed consent obtained per Institution Review Board/Ethics Committee requirements.

Exclusion Criteria

1. Stenosis, excessive tortuosity, or any occlusion in a proximal vessel requiring treatment or preventing access to the thrombus.
2. Alberta Stroke Program Early Computed Tomography Score (ASPECTS) ≤6 or core infarct volume >50 mL on magnetic resonance imaging (MRI) or computed tomography (CT)-based imaging (for anterior circulation strokes).
3. Pregnant patient.
4. Life expectancy < 90 days due to comorbidities.
5. Current participation in an interventional drug or device study that may confound the results of this study. Studies requiring extended follow-up for products that were investigational but have since become commercially available are not considered investigational studies.
6. Other medical, behavioral, or psychological conditions that in the opinion of the Investigator could limit the patient's ability to participate in the study, including compliance with follow-up requirements, or that could impact the scientific integrity of the study.

Analysis populations

A total of 216 participants were enrolled from August 2022 to September 2024. The Intent-to-Treat (ITT) population includes all participants who were enrolled. Participants were considered enrolled once they or their representative have provided informed consent and all eligibility criteria have been confirmed regardless of whether or not Thunderbolt was used. Participants who were enrolled but did not receive intervention with the Penumbra System including Thunderbolt were followed out to 72 hours of enrollment or discharge (whichever comes first). One participant in the ITT population was not treated with the Thunderbolt Aspiration Tubing because the initial Penumbra Aspiration Pump used did not power on and this participant did not have procedural data collected, including baseline modified Thrombolysis in Cerebral Infarction (mTICI) score. As pre-specified in the clinical protocol, this participant was followed out to 72 hours of enrollment or discharge (whichever came first) for safety.

The per-protocol (PP) population is defined as a subset of the ITT population. The PP population includes all participants that received intervention and did not have major protocol deviations. The eligibility criteria were not met in 13 participants, and Thunderbolt was not used in 2 participants [the Penumbra Aspiration Pump would not turn on (n=1 participant) and the Thunderbolt Aspiration Tubing could not be primed and continuous aspiration was used (n=1 participant)]. The remaining 201 participants were included in the Per-Protocol (PP) analysis. This is a secondary analysis population for the primary effectiveness outcome.

For the THUNDER study ITT population, the rate of participants with baseline mTICI 0-1 was 84.7% (183/216), baseline mTICI 2a was 11.6% (25/216), and baseline mTICI 2b-3 was 3.7% (8/216). For the Penumbra 3D study used to derive the performance goal for the THUNDER study, the rate of participants with baseline mTICI 0-1 was 93.9% (185/197), baseline mTICI 2a was 5.1% (10/197) of participants, and baseline mTICI 2b-3 was 1.0% (2/197) of participants. Additional analyses of the effectiveness endpoints

were also conducted for the population of THUNDER study participants with core lab adjudicated baseline mTICI 0-1 (n=183).

Participant Follow-up

Participants were assessed at baseline, during the procedure, 24 hours, 7-10 days or discharge, 30 days, and 90 days post-procedure. As outlined below, the 24-hour post-procedure assessment was completed in 99.1% (214/216) and the final 90-day follow-up visit was completed in 83.8% (181/216) of the ITT population.

Participant Follow-Up Visits, ITT Population

Participant follow-up visits	All Participants (N=216)
Baseline Evaluation	100.0% (216/216)
Procedure	99.5% (215/216)
24 Hours Follow-Up (± 12 hours)	99.1% (214/216)
7-10 Days Follow-Up and/or Discharge (whichever comes first)	94.9% (205/216)
30 Days Follow-Up (± 7 days)	87.0% (188/216)
90 Days Follow-Up (± 14 days)	83.8% (181/216)
Subject completed the study and alive[1]	84.3% (182/216)
Discontinued from the study	
Death	11.1% (24/216)
Lost to Follow-Up	4.2% (9/216)
Subject Withdrew Consent	0.5% (1/216)

[1] One participant did not receive intervention with the Penumbra System including Thunderbolt and completed the study at 72 hours post-procedure

Baseline Demographics, ITT Population

Baseline Demographics	All Participants (N=216)
Age	N = 216
Mean (SD)	64.8 (11.55)
Median [IQR]	68.0 [56.0, 74.5]
Sex at birth	**% (n/N)**
Female	45.4% (98/216)
Male	54.6% (118/216)
Ethnicity	**% (n/N)**
Hispanic or Latino	10.6% (23/216)
Not Hispanic or Latino	78.2% (169/216)
Not Reported	11.1% (24/216)
Race[1]	**% (n/N)**
American Indian or Alaska Native	0.5% (1/216)
Asian	1.4% (3/216)
Black	18.5% (40/216)
Native Hawaiian or Other Pacific Islander	0.5% (1/216)
White	74.1% (160/216)
Other	2.3% (5/216)
Unknown	0.9% (2/216)
Not Reported	1.9% (4/216)
Height, Weight, Body Mass Index (BMI) and Blood Pressure (BP)	**Mean (SD)**
Height (cm)	171.5 (10.27)
Weight (kg)	87.8 (22.21)

Baseline Demographics	All Participants (N=216)
BMI (kg/m^2)	29.8 (6.96)
Systolic BP (mmHg)	144.5 (24.88)
Diastolic BP (mmHg)	82.3 (16.43)
Pre-stroke mRS	**% (n/N)**
0	80.1% (173/216)
1	11.6% (25/216)
2	7.9% (17/216)
4	0.5% (1/216)
0 – 2	99.5% (215/216)
Occlusion Location[4]	**% (n/N)**
Anterior Circulation	96.7% (208/215)
Occlusion side	
Left	43.7% (94/215)
Right	53.0% (114/215)
Occlusion location	
ICA Origin	0.5% (1/215)
ICA Petrous	0.5% (1/215)
ICA Supraclinoid	2.3% (5/215)
Carotid T	6.0% (13/215)
M1	59.5% (128/215)
M2	27.4% (59/215)
Other[2]	0.5% (1/215)
Posterior Circulation	3.3% (7/215)
Occlusion side	
Left	0.0% (0/215)
Right	0.5% (1/215)
Midline/Basilar	2.8% (6/215)
Occlusion location	
Basilar	2.8% (6/215)
Other[3]	0.5% (1/215)
mTICI at Baseline per Core Lab[4]	**% (n/N)**
Grade 0-1	84.7% (183/216)
Grade 2a	11.6% (25/216)
Grade 2b-3	3.7% (8/216)
Baseline ASPECT score[5]	**N = 205**
Mean (SD)	9.2 (1.00)
Median [IQR]	10.0 [8.0, 10.0]
Minimum, Maximum	7.0, 10.0
Baseline PC ASPECT score[5]	**N = 7**
Mean (SD)	9.9 (0.38)
Median [IQR]	10.0 [10.0, 10.0]
Minimum, Maximum	9.0, 10.0
Baseline NIHSS Score	**N = 216**
Mean (SD)	14.4 (6.84)
Median [IQR]	15.0 [9.0, 20.0]
Minimum, Maximum	0.0, 38.0
Time from Stroke Onset to Arterial Puncture (minutes)[4]	**N = 215**
Mean (SD)	219 (108)
Median [IQR]	184 [143, 277]

Baseline Demographics	All Participants (N=216)

[1]Participants who selected the option Asian Indian, Chinese, Japanese, Korean, Vietnamese, Other Asian are categorized under Asian.
[2]Anterior circulation Left Occlusion side in the Occlusion Location: Other, specify – Lt ICA/M1.
[3]Posterior circulation Right Occlusion side in the Occlusion Location: Other, specify – P1, Pre communicating segment.
[4]One participant did not receive treatment with the Penumbra System including Thunderbolt. This participant did not have procedure data reported and was assigned baseline mTICI Grade 0-1.
[5]Three participants were missing ASPECT score. Data entry is completed for the three participants on core infarct size based on perfusion imaging. Each participant is required to have ASPECT/PC ASPECT or core infarct size measurement.

Devices used

Thunderbolt was used at the site of primary target vessel occlusion in 99.1% (214/216) of participants in the ITT population. Of the 216 ITT participants, 211 participants had modulated aspiration used in the first pass. Of the 211 participants with modulated aspiration used in the first pass, 61 participants (28.9%) had one or more continuous aspiration passes performed with Thunderbolt after the first pass with modulated aspiration.

The reperfusion catheter used with Thunderbolt at the site of the primary target vessel occlusion at any pass was RED 62, RED 68 and RED 72 in 40.5% (87/215), 36.7% (79/215), and 38.6% (83/215) of participants, respectively. Note that participants could have been treated with more than 1 model of the RED catheter during the procedure.

Procedural Characteristics, ITT Population

Procedural characteristics	All Participants (N=216)
Use of additional therapy During Procedure	**% (n/N)**
Any additional therapy[1]	**14.4% (31/215)**
Non-Penumbra aspiration catheter	3.3% (7/215)
Stent retriever	9.3% (20/215)
Penumbra 3D Revascularization Device	1.4% (3/215)
Balloon angioplasty	1.9% (4/215)
Stent	3.3% (7/215)
Time from Arterial Puncture to mTICI 2b-3 otherwise to Final Angiogram (minutes) per Principal Investigator (PI) (mTICI assessment per Core Lab)[2]	**N = 214**
Mean (SD)	27 (26)
Median [IQR]	20 [13, 29]
Minimum, Maximum	4, 240
Time from Initial Aspiration Start to mTICI 2b-3 otherwise to Final Angiogram (minutes)[2]	**N = 214**
Mean (SD)	11 (21)
Median [IQR]	4 [2, 10]
Minimum, Maximum	0, 189
Time from Arterial Puncture to Final Angiogram (minutes)[2]	**N = 214**
Mean (SD)	37 (31)
Median [IQR]	27 [17, 46]
Minimum, Maximum	5, 240
Total number of passes	**N = 216**
Mean (SD)	2.3 (1.82)
Median [IQR]	2.0 [1.0, 3.0]
Minimum, Maximum	1.0, 13.0

Procedural characteristics	All Participants (N=216)
Thrombolytic Therapy	**% (n/N)**
Received thrombolytic therapy prior to procedure	**56.9% (123/216)**
Bridging protocol	93.5% (115/123)
Waiting for improvement	6.5% (8/123)

[1]One participant did not receive intervention with the Penumbra System including Thunderbolt and did not report devices used. Participants can have more than one type of additional therapy used during procedure. Additional therapies could have been utilized for reasons other than to achieve successful revascularization of the target vessel.
[2]Two participants did not have an end of procedure angiographic outcome per Core Lab. One participant did not receive intervention with the Penumbra System including Thunderbolt and did not collect angiographic images; one participant had angiographic images but had "Unable to Assess" assessment for final angiogram.

Results

Effectiveness

The primary effectiveness endpoint was angiographic revascularization of the occluded target vessel at immediate post-Penumbra procedure as defined by mTICI 2b or higher. A performance goal of 71.5% was pre-defined for the THUNDER study derived from the 95% lower confidence bound of the rate of mTICI 2b or higher in the full ITT population (both study arms) of the Penumbra 3D trial. An exact binomial test, conducted at the 0.025 one-sided significance level, was used to test the null hypothesis that the population proportion of patients with post-Penumbra revascularization success is less than or equal to the performance goal of 71.5%, against the alternative hypothesis that the proportion is greater than 71.5%.

The primary effectiveness endpoint of angiographic revascularization (mTICI 2b-3) of the occluded target vessel at immediate post-Penumbra was achieved in 87.5% (189/216) of participants. The lower bound of the 95% confidence interval was 82.3%, rejecting the null hypothesis that the study rate is less than or equal to 71.5% (p-value: <0.001). Therefore, THUNDER met its pre-defined performance goal for the primary effectiveness endpoint.

The following supplementary analyses were also conducted: (1) imputing participants with first pass continuous (non-modulated) aspiration as failures; (2) imputing participants with first pass continuous (non-modulated) aspiration, the number of RED catheter passes >5, or any adjunctive device use as failures. These analyses resulted in success rates of 86.6% (187/216), and 78.7% (170/216) with corresponding lower bounds of the 95% confidence intervals of 81.3%, and 72.6%, respectively. These were all greater than the performance goal of 71.5%.

Primary Effectiveness Endpoint, ITT Population

Primary endpoint success	ITT Participants, (95% CI)[1] (N=216)
mTICI 2b-3 Post-Penumbra per Core Lab[2]	87.5% (189/216) (82.3%, 91.6%)
mTICI 2b-3 Post-Penumbra per Core Lab[2], imputing participants with first pass continuous (non-modulated) aspiration as failure	86.6% (187/216) (81.3%, 90.8%)
mTICI 2b-3 Post-Penumbra per Core Lab[2], imputing participants with first pass continuous (non-modulated) aspiration, number of RED catheter passes >5, or any use of adjunctive treatment (3D Revascularization Device, non-Penumbra aspiration catheter, stent retriever, balloon angioplasty, stent) as failure	78.7% (170/216) (72.6%, 84.0%)

Note: Participants not treated with Thunderbolt are analyzed as endpoint failure in all mTICI analyses.
[1]Clopper Pearson Binomial method is used for proportion 95% CI.
[2]Success is revascularization of the occluded target vessel defined by mTICI score of 2b to 3 following use of the Penumbra System (immediate post-Penumbra) and prior to the use of any additional therapies or adjunctive devices. Participants with intracranial stenosis/atherosclerosis (ICAD) treated with stenting or angioplasty at primary target vessel occlusion location prior to achieving mTICI 2b or greater are analyzed as effectiveness endpoint failures.

Additional analyses of the primary effectiveness endpoint were also conducted in the PP population. See the table below.

Primary Effectiveness Endpoint, PP Population

Primary endpoint success	PP Participants, (95% CI)[1] (N=201)
mTICI 2b-3 Post-Penumbra per Core Lab[2]	89.1% (179/201) (83.9%, 93.0%)
mTICI 2b-3 Post-Penumbra per Core Lab[2], imputing participants with first pass continuous (non-modulated) aspiration as failure	88.6% (178/201) (83.3%, 92.6%)
mTICI 2b-3 Post-Penumbra per Core Lab[2], imputing participants with first pass continuous (non-modulated) aspiration, number of RED catheter passes >5, or any use of adjunctive treatment (3D Revascularization Device, non-Penumbra aspiration catheter, stent retriever, balloon angioplasty, stent) as failure	80.6% (162/201) (74.4%, 85.8%)

Note: Participants not treated with Thunderbolt are analyzed as endpoint failure in all mTICI analyses.
[1]Clopper Pearson Binomial method is used for proportion 95% CI.
[2]Success is revascularization of the occluded target vessel defined by mTICI score of 2b to 3 following use of the Penumbra System (immediate post-Penumbra) and prior to the use of any additional therapies or adjunctive devices. Participants with intracranial stenosis/atherosclerosis (ICAD) treated with stenting or angioplasty at primary target vessel occlusion location prior to achieving mTICI 2b or greater are analyzed as effectiveness endpoint failures.

Primary Effectiveness Endpoint, mTICI 0-1 at Baseline Population

Primary endpoint success	mTICI 0-1 at Baseline Participants, (95% CI)[1] (N=183)
mTICI 2b-3 Post-Penumbra per Core Lab[2]	86.9% (159/183) (81.1%, 91.4%)
mTICI 2b-3 Post-Penumbra per Core Lab[2], imputing participants with first pass continuous (non-modulated) aspiration as failure	85.8% (157/183) (79.9%, 90.5%)
mTICI 2b-3 Post-Penumbra per Core Lab[2], imputing participants with first pass continuous (non-modulated) aspiration, number of RED catheter passes >5, or any use of adjunctive treatment (3D Revascularization Device, non-Penumbra aspiration catheter, stent retriever, balloon angioplasty, stent) as failure	77.0% (141/183) (70.3%, 82.9%)

Note: Participants not treated with Thunderbolt are analyzed as endpoint failure in all mTICI analyses. One participant without procedure data reported was assigned baseline mTICI Grade 0-1.
[1]Clopper Pearson Binomial method is used for proportion 95% CI.
[2]Success is revascularization of the occluded target vessel defined by mTICI score of 2b to 3 following use of the Penumbra System (immediate post-Penumbra) and prior to the use of any additional therapies or adjunctive devices. Participants with intracranial stenosis/atherosclerosis (ICAD) treated with stenting or angioplasty at primary target vessel occlusion location prior to achieving mTICI 2b or greater are analyzed as efficacy endpoint failures.

Other effectiveness outcomes for the ITT population are provided in the table below. After the first pass, mTICI 2b or higher per Core Lab was achieved in 64.8% (140/216). Post-Penumbra, mTICI 2c or higher per Core Lab was achieved in 70.4% (152/216) of participants. At the end of the procedure, mTICI 2b or higher per Core Lab was achieved in 96.3% (206/214). Two participants did not have an end of procedure angiographic outcome per Core Lab. The median time to revascularization was 20 minutes. At 90 days, 55.4% (112/202) of participants had mRS 0-2.

Other Effectiveness Outcomes, ITT Population

	ITT Participants, (95% CI)[1] (N=216)
Angiographic outcomes	
Angiographic revascularization of the occluded target vessel after first pass as defined by mTICI 2b or higher per Core Lab[2,3]	64.8% (140/216) (55.5%, 73.4%)
Angiographic revascularization of the occluded target vessel Post-Penumbra as defined by mTICI 2c or higher per Core Lab[2,3]	70.4% (152/216) (61.3%, 78.4%)
Angiographic revascularization of the occluded target vessel at end of procedure as defined by mTICI 2b or higher per Core Lab[4]	96.3% (206/214)
Time to revascularization (time from arterial puncture to mTICI 2b-3 otherwise to final angiogram, minutes)	
N[4]	214
Mean (SD) (95% CI)[3,5]	27 (26) (59, 122)
Median [IQR]	20 [13, 29]
Range (Min, Max)	4, 240
Clinical outcome	
Modified Rankin Scale (mRS) 0-2 at 90 days[3,6]	55.4% (112/202) (45.7%, 64.9%)

	ITT Participants, (95% CI)[1] (N=216)

[1]Clopper Pearson Binomial method is used for proportion 95% CI.
[2]Participants not treated with Thunderbolt are analyzed as endpoint failure.
[3]Confidence intervals are adjusted for multiplicity using the Bonferroni method (k=7).
[4]Two participants did not have an end of procedure angiographic outcome per Core Lab. One participant did not receive intervention with the Penumbra System including Thunderbolt and did not collect angiographic images; one participant had angiographic images but had "Unable to Assess" assessment for final angiogram.
[5]Wald normal approximation to the binomial distribution confidence intervals are presented.
[6]Denominator is out of all completed mRS 90-day follow-up assessments and includes reported deaths. Missing data for 90-day mRS includes 9 participants lost-to-follow-up, 1 participant withdrew consent, 3 participants with missed mRS assessment at 90 days. One participant did not receive intervention with the Penumbra System including Thunderbolt and completed the study at 72 hours.

Other effectiveness outcomes for the PP population are provided in the table below. After the first pass, mTICI 2b or higher per Core Lab was achieved in 65.2% (131/201). Post-Penumbra, mTICI 2c or higher per Core Lab was achieved in 71.6% (144/201) of participants. At the end of the procedure, mTICI 2b or higher per Core Lab was achieved in 96.0% (192/200). One participant did not have an end of procedure angiographic outcome per Core Lab. The median time to revascularization was 19 minutes. At 90 days, 55.9% (105/188) of participants had mRS 0-2.

Other Effectiveness Outcomes, PP Population

	PP Participants, (95% CI)[1] (N=201)
Angiographic outcomes	
Angiographic revascularization of the occluded target vessel after first pass as defined by mTICI 2b or higher per Core Lab[2]	65.2% (131/201) (55.6%, 74.0%)
Angiographic revascularization of the occluded target vessel Post-Penumbra as defined by mTICI 2c or higher per Core Lab[2]	71.6% (144/201) (62.3%, 79.8%)
Angiographic revascularization of the occluded target vessel at end of procedure as defined by mTICI 2b or higher per Core Lab[3]	96.0% (192/200)
Time to revascularization (time from arterial puncture to mTICI 2b-3 otherwise to final angiogram, minutes)	
N[3]	200
Mean (SD) (95% CI)[2,4]	27 (26) (59, 151)
Median [IQR]	19 [13, 29]
Range (Min, Max)	4, 240
Clinical outcome	
Modified Rankin Scale (mRS) 0-2 at 90 days[2,5]	55.9% (105/188) (45.8%, 65.6%)

[1]Clopper Pearson Binomial method is used for proportion 95% CI.
[2]Confidence intervals are adjusted for multiplicity using the Bonferroni method (k=7).
[3]One participant had "Unable to Assess" assessment for final angiogram.
[4]Wald normal approximation to the binomial distribution confidence intervals are presented.
[5]Denominator is out of all completed mRS 90-day follow-up assessments and includes reported deaths. Missing data for 90-day mRS includes 8 participants lost-to-follow-up, 1 participant withdrew consent, 3 participants with missed mRS assessment at 90 days. One participant did not receive treatment with the Penumbra System including Thunderbolt and completed the study at 72 hours.

Other Effectiveness Outcomes, mTICI 0-1 at Baseline Population

	mTICI 0-1 at Baseline Participants, (95% CI)[1] (N=183)
Angiographic outcomes	
Angiographic revascularization of the occluded target vessel after first pass as defined by mTICI 2b or higher per Core Lab[2]	60.1% (110/183) (49.9%, 69.7%)

	mTICI 0-1 at Baseline Participants, (95% CI)[1] (N=183)
Angiographic revascularization of the occluded target vessel Post-Penumbra as defined by mTICI 2c or higher per Core Lab[2]	68.3% (125/183) (58.3%, 77.2%)
Angiographic revascularization of the occluded target vessel at end of procedure as defined by mTICI 2b or higher per Core Lab[3]	95.6% (173/183)
Time to revascularization (time from arterial puncture to mTICI 2b-3 otherwise to final angiogram, minutes)	
N[3]	181
Mean (SD) (95% CI)[2,4]	28 (28) (66, 122)
Median [IQR]	21 [13, 30]
Range (Min, Max)	6, 240
Clinical outcome	
Modified Rankin Scale (mRS) 0-2 at 90 days[2,5]	54.1% (92/170) (46.3%, 61.8%)

Note: One participant without procedure data reported was assigned baseline mTICI Grade 0-1.
[1]Clopper Pearson Binomial method is used for proportion 95% CI.
[2]Confidence intervals are adjusted for multiplicity using the Bonferroni method (k=7).
[3]One participant had "Unable to Assess" assessment for final angiogram. One participant did not receive treatment with the Penumbra System including Thunderbolt.
[4]Wald normal approximation to the binomial distribution confidence intervals are presented.
[5]Denominator is out of all completed mRS 90-day follow-up assessments and includes reported deaths. Missing data for 90-day mRS includes 8 participants lost-to-follow-up, 1 participant withdrew consent, 3 participants with missed mRS assessment at 90 days. One participant did not receive treatment with the Penumbra System including Thunderbolt and completed follow-up at 72 hours.

Safety

The safety of the Penumbra System including the Thunderbolt Aspiration Tubing was evaluated through a review of adverse events (AEs) recorded during the study. A summary of key safety metrics is provided below.

In comparing THUNDER with the Penumbra 3D study, the rate of participants that had additional passes due to additional clot in distal vasculature was 20.8% (45/216) in THUNDER and 16.7% (33/198) in the Penumbra 3D study. The rate of serious adverse events (SAEs) classified as embolization to a new territory (ENT) per Clinical Events Committee (CEC) was 0.5% (1/216) in THUNDER. ENT was not assessed by the CEC in the Penumbra 3D study.

Key Safety Outcomes, ITT Population

	ITT Participants, (95% CI)[1] (N=216)
Occurrence of symptomatic intracranial hemorrhages (sICH) at 24 Hours per CEC	0.9% (2/216) (0.0%, 4.4%)
All-cause mortality at 90 days[2]	11.7% (24/205) (6.4%, 19.0%)
Incidence of device related, and/or procedure related Serious Adverse Events (SAEs) within 24 hours post-procedure per CEC[3]	2.8% (6/216) (0.7%, 7.3%)

	ITT Participants, (95% CI)[1] (N=216)
[1]Clopper Pearson Binomial method is used for proportion 95% CI. Confidence intervals are adjusted for multiplicity using the Bonferroni method (k=7). [2]Denominator is out of all completed mRS 90-day follow-up assessments and includes reported deaths. Missing data for 90-day mRS includes 9 participants lost-to-follow-up, 1 participant withdrew consent, 3 participants with missed mRS assessment at 90 days. One participant did not receive treatment with the Penumbra System including Thunderbolt and completed follow-up at 72 hours. [3]Includes symptomatic intracerebral hemorrhage, embolization to a new territory, and intracranial vascular injury (e.g. dissection or perforation).	

Images were reviewed and imaging findings of ICH within 24 hours – irrespective of clinical significance – were identified by the core lab and classified using ECASS classification.

ICH by ECASS Classification (Core Lab), ITT Population

	ITT Participants (N=214)
Total Intracranial Hemorrhage within 24 hours per Core Lab	**26.6% (57/214)**
IPH: HI-2	8.4% (18/214)
IPH: HI-1	6.1% (13/214)
SAH	4.7% (10/214)
IPH: HI-2 + SAH	2.8% (6/214)
IPH: PH-1	0.9% (2/214)
IPH: PH-1 + IVH + SAH	0.9% (2/214)
IPH: HI-1 + SAH	0.5% (1/214)
IPH: HI-2 + IVH + SAH	0.5% (1/214)
RIH	0.5% (1/214)
IPH: PH-2 + SAH	0.5% (1/214)
IPH: PH-2 + IVH	0.5% (1/214)
IPH: PH-2	0.5% (1/214)
Note: Two participants with missing 24-hour imaging are excluded from intracranial hemorrhage summary.	

Adverse events categorized under the nervous system disorders MedDRA System Organ Class are summarized below for the ITT population.

MedDRA Classification of Adverse Events, Nervous System Disorders, ITT Population

MedDRA classification (Participants, N = 216)[1]		
	Events (participants)	**Rate of participants with event**
Nervous system disorders	**140 (105)**	**48.6%**
Basal ganglia haemorrhage	2 (2)	0.9%
Brain compression	2 (2)	0.9%
Brain oedema	7 (7)	3.2%
Carotid artery dissection	2 (2)	0.9%
Carotid artery occlusion	2 (2)	0.9%
Carotid artery stenosis	1 (1)	0.5%
Cerebellar infarction	1 (1)	0.5%
Cerebellar stroke	1 (1)	0.5%

Cerebral artery embolism	3 (3)	1.4%
Cerebral artery occlusion	5 (5)	2.3%
Cerebral artery perforation	1 (1)	0.5%
Cerebral artery stenosis	1 (1)	0.5%
Cerebral artery thrombosis	1 (1)	0.5%
Cerebral haematoma	1 (1)	0.5%
Cerebral haemorrhage	13 (13)	6.0%
Cerebral infarction	7 (7)	3.2%
Cerebral microangiopathy	1 (1)	0.5%
Cerebral vasoconstriction	9 (9)	4.2%
Cerebrovascular accident	2 (2)	0.9%
Dysarthria	1 (1)	0.5%
Encephalopathy	2 (2)	0.9%
Haemorrhage intracranial	3 (3)	1.4%
Haemorrhagic transformation stroke	13 (13)	6.0%
Headache	16 (15)	6.9%
Hemiparesis	1 (1)	0.5%
Hyperaesthesia	1 (1)	0.5%
Intracranial artery dissection	1 (1)	0.5%
Ischaemic cerebral infarction	1 (1)	0.5%
Ischaemic stroke	2 (2)	0.9%
Metabolic encephalopathy	3 (3)	1.4%
Neuropathy peripheral	1 (1)	0.5%
Partial seizures	1 (1)	0.5%
Restless legs syndrome	1 (1)	0.5%
Seizure	7 (7)	3.2%
Stroke in evolution	15 (15)	6.9%
Subarachnoid haemorrhage	5 (5)	2.3%
Syncope	2 (2)	0.9%
Toxic encephalopathy	2 (2)	0.9%
[1]MedDRA reflects site-reported adverse events. Therefore, some core-lab identified ICH findings (which are imaging-based, and irrespective of clinical significance) may not be captured as MedDRA events. Site-reported hemorrhagic events, as coded using MedDRA terminology, are independent of core lab imaging assessments and do not necessarily correspond to core-lab identified ICH.		

THUNDER Study Conclusions

The THUNDER study demonstrated that the Penumbra System including Thunderbolt Aspiration Tubing has substantially equivalent safety and effectiveness for the revascularization of patients with acute ischemic stroke secondary to intracranial large vessel occlusion compared to the predicate. The THUNDER study met its prespecified primary effectiveness endpoint.

9. Conclusions

The subject Penumbra System (Thunderbolt Aspiration Tubing) is substantially equivalent to the predicate Penumbra System (Modified 110 Aspiration Tubing). The subject device has the same intended use and similar operating principle, design concept, and fundamental technology as the predicate. The differences between the subject and predicate devices do not raise new or different questions of safety or effectiveness. The

device testing described in this 510(k) Summary demonstrates the subject device performs as intended.