



March 27, 2024

Penumbra, Inc.
Sheina Rajkumar
Regulatory Affairs Specialist II
One Penumbra Place
Alameda, California 94502

Re: K233201

Trade/Device Name: MIDWAY Delivery Catheter (MIDWAY 43 Delivery Catheter; MIDWAY 62 Delivery Catheter)
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous Catheter
Regulatory Class: Class II
Product Code: QJP, DQY
Dated: February 21, 2024
Received: February 22, 2024

Dear Sheina Rajkumar:

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.

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, 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

Indications for Use

510(k) Number (if known)
K233201

Device Name

MIDWAY Delivery Catheter (MIDWAY 43 Delivery Catheter; MIDWAY 62 Delivery Catheter)

Indications for Use (Describe)

The MIDWAY Delivery Catheter is indicated for the introduction of interventional devices into the peripheral, coronary, 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.

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510(k) Summary

1. Submitter

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Date of Preparation:
 March 26, 2024

2. Subject Device

MIDWAY Delivery Catheter (MIDWAY 43 Delivery Catheter; MIDWAY 62 Delivery Catheter)

Classification Name: Catheter, Percutaneous, Neurovasculature
 Regulation Number: 21 CFR 870.1250 - Class II
 Product Code: QJP, DQY

3. Predicate/Reference Devices

MIDWAY 43 Delivery Catheter		
Predicate	K070970	Neuron Intracranial Access System
Reference	K222808	Penumbra System (Reperfusion Catheter RED 43)
MIDWAY 62 Delivery Catheter		
Predicate	K142321	Benchmark Intracranial Access System
Reference	K203440	Penumbra System (Reperfusion Catheter RED 62)

4. Device Description

The MIDWAY Delivery Catheters are single lumen percutaneous catheters designed to provide a conduit for introduction of interventional devices to the peripheral, coronary, and neuro vasculature. The MIDWAY Delivery Catheters include the following:

- MIDWAY 43 Delivery Catheter
- MIDWAY 62 Delivery Catheter

The MIDWAY Delivery Catheter is a single lumen, coil-reinforced, variable stiffness catheter with a radiopaque marker band on the distal end and a Luer hub on the proximal end. The MIDWAY Delivery Catheter is compatible with sheaths and guide catheters appropriately sized for the outer diameter of the MIDWAY Delivery Catheter. The MIDWAY Delivery Catheter has a hydrophilic coating on the distal segment of the catheter shaft.

5. Indications For Use

The MIDWAY Delivery Catheter is indicated for the introduction of interventional devices into the peripheral, coronary, and neuro vasculature.

6. Comparison of Technological Characteristics with the Predicate and Reference Devices

Device Name	Neuron Intracranial Access System [Predicate]	Penumbra System (Reperfusion Catheter RED 43) [Reference]	MIDWAY 43 Delivery Catheter [Subject]	Comparison
Classification	Class II, DQY	Class II, NRY	Class II, QJP, DQY	N/A
510(k) Number	K070970	K222808	K233201	N/A
Indications for Use	The Neuron™ Intracranial Access System is indicated for the introduction of interventional devices into the peripheral, coronary, and neuro vasculature.	<u>Penumbra Reperfusion Catheters and Separators</u> 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. <u>Penumbra 3D Revascularization Device</u> As part of the Penumbra System, the Penumbra 3D Revascularization Device is	The MIDWAY Delivery Catheter is indicated for the introduction of interventional devices into the peripheral, coronary, and neuro vasculature.	SAME as Predicate Device [K070970]

Device Name	Neuron Intracranial Access System [Predicate]	Penumbra System (Reperfusion Catheter RED 43) [Reference]	MIDWAY 43 Delivery Catheter [Subject]	Comparison
		<p>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.</p> <p><u>Penumbra Aspiration Tubing</u> As part of the Penumbra System, the Penumbra Sterile Aspiration Tubing is indicated to connect the Penumbra Reperfusion Catheters to the Penumbra Aspiration Pump.</p> <p><u>Penumbra Aspiration Pump</u> The Penumbra Aspiration Pump is indicated as a vacuum source for Penumbra Aspiration Systems.</p>		
Materials	Stainless Steel, PTFE, Polyurethane, Polyether Block Amide, Nylon, Platinum/Iridium	Stainless Steel, PTFE, Polyurethane, Polyether Block Amide, Nylon 12, Nitinol, Platinum/Iridium	Stainless Steel, PTFE, Polyurethane, Polyether Block Amide, Nylon 12, Nitinol, Platinum/Iridium	SAME as Reference Device [K222808]
Coating	Hydrophilic (proprietary)	Hydrophilic (proprietary)	Hydrophilic (proprietary)	SAME as Reference Device [K222808]
Distal Inner Diameter (ID)	0.053 in Min	0.043 in Min	0.043 in Min	SAME as Reference Device [K222808]
Proximal ID	0.053 in Min	0.043 in Min	0.043 in Min	SAME as Reference Device [K222808]
Distal Outer Diameter (OD)	0.072 in Max	0.056 in Max	0.056 in Max	SAME as Reference Device [K222808]
Proximal OD	0.083 in Max	0.060 in Max	0.060 in Max	SAME as Reference Device [K222808]

Device Name	Neuron Intracranial Access System [Predicate]	Penumbra System (Reperfusion Catheter RED 43) [Reference]	MIDWAY 43 Delivery Catheter [Subject]	Comparison
Effective Lengths	105, 115 cm	115, 120, 125, 127, 132, 136, 138, 145, 150, 153, 155, 160, 162, 167 cm	115, 120, 125, 127, 136, 138, 160, 162, 167 cm	SAME
Packaging Materials	Polyester/Polyethylene/Tyvek, Polyethylene, SBS Paperboard.	Polyester/Polyethylene/Tyvek, Polystyrene, SBS Paperboard	Polyester/Polyethylene/Tyvek, SBS Paperboard	SAME
Sterilization	Ethylene Oxide (EO)	EO	EO	SAME
Shelf-Life	36 Months	36 Months	36 Months	SAME
Single Use	Single use	Single use	Single use	SAME

Device Name	Benchmark Intracranial Access System [Predicate]	Penumbra System (Reperfusion Catheter RED 62) [Reference]	MIDWAY 62 Delivery Catheter [Subject]	Comparison
Classification	Class II, DQY	Class II, NRY	Class II, QJP, DQY	N/A
510(k) Number	K142321	K203440	K233201	N/A
Indications for Use	The Benchmark™ Intracranial Access System is indicated for the introduction of interventional devices into the peripheral, coronary, and neuro vasculature.	<p><u>Penumbra Reperfusion Catheters and Separators</u> 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.</p> <p><u>Penumbra 3D Revascularization Device</u> As part of the Penumbra System, the Penumbra 3D Revascularization Device is indicated for use in the revascularization of patients with acute ischemic stroke secondary to intracranial large vessel occlusive disease (within the internal carotid,</p>	The MIDWAY Delivery Catheter is indicated for the introduction of interventional devices into the peripheral, coronary, and neuro vasculature.	SAME as Predicate Device [K142321]

Device Name	Benchmark Intracranial Access System [Predicate]	Penumbra System (Reperfusion Catheter RED 62) [Reference]	MIDWAY 62 Delivery Catheter [Subject]	Comparison
		<p>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.</p> <p><u>Penumbra Aspiration Tubing</u> As part of the Penumbra System, the Penumbra Sterile Aspiration Tubing is indicated to connect the Penumbra Reperfusion Catheters to the Penumbra Aspiration Pump.</p> <p><u>Penumbra Aspiration Pump</u> The Penumbra Aspiration Pump is indicated as a vacuum source for Penumbra Aspiration Systems.</p>		
Materials	Stainless Steel, PTFE, Polyurethane, Polyether Block Amide, Nylon, Platinum/Tungsten	Stainless Steel, PTFE, Polyurethane, Polyether Block Amide, Nylon 12, Nitinol, Platinum/Iridium	Stainless Steel, PTFE, Polyurethane, Polyether Block Amide, Nylon 12, Nitinol, Platinum/Iridium	SAME as Reference Device [K203440]
Coating	Hydrophilic (proprietary)	Hydrophilic (proprietary)	Hydrophilic (proprietary)	SAME as Reference Device [K203440]
Distal ID	0.070 in Min	0.062 in Min	0.062 in Min	SAME as Reference Device [K203440]
Proximal ID	0.070 in Min	0.062 in Min	0.062 in Min	SAME as Reference Device [K203440]
Distal OD	0.083 in Max	0.076 in Max	0.076 in Max	SAME as Reference Device [K203440]
Proximal OD	0.083 in Max	0.076 in Max	0,076 in Max	SAME as Reference Device [K203440]
Effective Lengths	95, 105, 115 cm	115, 120, 125, 127, 132, 138, 160 cm	115, 120, 125, 132, 138, 160 cm	SAME
Packaging Materials	Polyester/Polyethylene /Tyvek, Polyethylene,	Polyester/Polyethylene/	Polyester/Polyethylene/ Tyvek, SBS Paperboard	SAME

Device Name	Benchmark Intracranial Access System [Predicate]	Penumbra System (Reperfusion Catheter RED 62) [Reference]	MIDWAY 62 Delivery Catheter [Subject]	Comparison
	SBS Paperboard	Tyvek, Polystyrene, SBS Paperboard		
Sterilization	EO	EO	EO	SAME
Shelf-Life	36 Months	36 Months	36 Months	SAME
Single Use	Single use	Single use	Single use	SAME

7. Bench Performance Testing

The subject MIDWAY 43 Delivery Catheter and MIDWAY 62 Delivery Catheter have the same design, materials, and manufacturing as the respective reference devices:

Reperfusion Catheter RED 43 (K222808) and Reperfusion Catheter RED 62 (K203440).

Bench performance testing of the reference devices was used in support of the subject device. The following additional bench performance testing was conducted to support the new indication of the subject catheters:

Test	Test Method Summary	Conclusion
Simulated Use Test	Confirms the functionality of MIDWAY Delivery Catheters using clinically relevant benchtop model, including testing with a marketed stent-retriever.	Acceptance Criteria Met
Compatibility Test	Confirms compatibility of MIDWAY Delivery Catheters with a marketed introducer sheath, guidewire, microcatheter, and stent-retriever.	Acceptance Criteria Met
Particulate Test	Particulates generated during simulated use were evaluated.	Acceptance Criteria Met
Coating Integrity Test	Confirms that coating of MIDWAY Delivery Catheters has not delaminated, peeled, or flaked before or after simulated use.	Acceptance Criteria Met
Surface Integrity	The MIDWAY Delivery Catheter surface is inspected for defects.	Acceptance Criteria Met
Tensile Strength Test	Confirms MIDWAY Delivery Catheters meet product specification related to tensile strength after simulated use.	Acceptance Criteria Met
Burst Pressure Test	Confirms MIDWAY Delivery Catheters can withstand sufficient pressure after simulated use.	Acceptance Criteria Met

8. Other Performance Data

The subject MIDWAY 43 Delivery Catheter and MIDWAY 62 Delivery Catheter have the same design, materials, and manufacturing as the respective reference devices: Reperfusion Catheter RED 43 (K222808) and Reperfusion Catheter RED 62 (K203440). The following testing of the reference devices was used in support of the subject device:

- Biocompatibility
- Shelf Life
- Sterilization
- Packaging

9. Animal and Clinical Data

No animal or clinical studies were deemed necessary to support the substantial equivalence of the MIDWAY Delivery Catheters.

10. Conclusions

The subject MIDWAY Delivery Catheters are substantially equivalent to the respective predicate devices (K070970 and K142321). The subject device has the same intended use as the predicate devices. The non-clinical testing demonstrates that the subject device performs as intended and is substantially equivalent to the predicate devices. The differences in technological characteristics of the subject and predicate devices do not raise new questions of safety or effectiveness.