November 20, 2024

Q'Apel Medical, Inc.
℅ Wanda Carpinella
Regulatory Consultant
Insight Medical, LLC
7 Barrows Road
Shrewsbury, Massachusetts 01545

Re: K240746
Trade/Device Name: Neurovascular Access System Family
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous Catheter
Regulatory Class: Class II
Product Code: QJP, DQY
Dated: October 25, 2024
Received: October 25, 2024

Dear Wanda Carpinella:

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,

Sara S. Thompson -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)*
K240746

Device Name
Neurovascular Access System Family

Indications for Use *(Describe)*
The Neurovascular Access System Family is indicated for the introduction of interventional devices into the peripheral and neuro vasculature. It is not intended for use in coronary arteries.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(k) Summary

Traditional Premarket Notification 510(k) Summary

Neurovascular Access System Family

510(k) Number K240746

Date Prepared: November 18, 2024

I. SUBMITTER

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II. DEVICE

Name of Device:	Neurovascular Access System Family
Common or Usual Name:	Neurovascular Access Catheter
Classification Regulation:	21 CFR § 870.1250
Regulation Name:	Percutaneous Catheter
Product Codes:	QJP, DQY
Regulatory Class:	II

III. PREDICATES

Primary predicate

- Benchmark Intracranial Access System, K212838

Secondary predicate

- SelectFlex Neurovascular Access System Family, K211893

IV. DEVICE DESCRIPTION

The subject Neurovascular Access System Family consists of sterile, single-use catheters and accessories that are used together to facilitate the insertion and guidance of an appropriately sized interventional device into a selected vessel in the peripheral and neurovasculature. The Neurovascular Access System is comprised of the Neurovascular Access Catheter, Access Tool, Peel Away Introducer and Dilator. The Neurovascular Access System Family is offered in various lengths to accommodate physician preferences and anatomical variations. The distal end of the catheter is coated with hydrophilic coating to reduce friction during use and a radiopaque marker on the distal tip that is visible under fluoroscopy.

V. INDICATIONS FOR USE

The Neurovascular Access System Family is indicated for the introduction of interventional devices into the peripheral and neuro vasculature. It is not intended for use in coronary arteries.

VI. COMPARISION OF TECHNOLOGICAL CHARACTERISICS WITH PREDICATES

The following table compares key features of the subject and predicate devices.

	Subject Device	Primary Predicate Device Benchmark Intracranial Access System K212838	Secondary Predicate Device SelectFlex Neurovascular Access System Family K211893	Comparison
Indication for Use	The Neurovascular Access System Family is indicated for the introduction of interventional devices into the peripheral and neurovasculature. It is not intended for use in coronary arteries.	The Benchmark Intracranial Access System is indicated for the introduction of interventional devices into the periphral, coronary, and neurovasculature.	The SelectFlex Neurovascular Access System Family is indicated for the introduction of interventional devices into the peripheral and neurovasculature.	Similar, the subject device limits the indications to introduction of interventional devices into the peripheral and neurovascular and peripheral, which are within the currently cleared indication statement of the predicate. Difference does not raise new questions of safety and effectiveness.
Product Code	DQY, QJP	DQY, QJP	DQY, QJP	Same
Classification	Class II	Class II	Class II	Same
Material	Catheter Body: Variable durometer outer polymer jacket that delivers a flexible distal shaft and transition to stiffer proximal section. Inner Liner: PTFE	Catheter Body: Variable durometer outer polymer jacket that delivers a flexible distal shaft and transition to stiffer proximal section.	Catheter Body: Variable durometer outer polymer jacket that delivers a flexible distal shaft and transition to stiffer proximal section. Inner Liner: PTFE User selected tracking and support modes	Similar, differences do not raise new questions of safety and effectiveness
Catheter Shaft Reinforcement	Laser cut stainless steel hypotube	Stainless steel coil	Stainless steel coil & nitinol scaffold	Similar, differences do not raise new questions of safety and effectiveness
Hydrophilic Coating	Yes – Distal portion	Yes – Distal portion	Yes – Distal portion	Same
Visibility under fluoroscopy	Yes Access Catheter marker band Access Tool Distal Tip	Yes Access Catheter marker band 5F Select Catheter Distal Tip	Yes Access Catheter marker band	Same
Working Length	074 Access Catheter: 80, 95, 105, 115 cm 087 Access Catheter: 80, 95, and 105 cm	95, 105, 115 cm	95, 105, and 115 cm	Similar, differences do not raise new questions of safety or effectiveness

	Subject Device	Primary Predicate Device Benchmark Intracranial Access System K212838	Secondary Predicate Device SelectFlex Neurovascular Access System Family K211893	Comparison
Outer Diameter	6French (F) and 7F	6F	7F	Same
Inner Diameter	0.074 and 0.087 inch	0.071 inch	0.072 inch	Similar, differences do not raise new questions of safety or effectiveness
Tip Shapes Offered	Straight	Straight & Multi-purpose	Straight	Same
Accessories Supplied	- Peel away introducer, - 5F and 6F Dilator, - 5F Access Tool in Simmons 2 and Berenstein distal shape	- 5F Select Catheter in Berenstein, H1, and Simmons distal shape	- 7 F Introducer Sheath, - 3cc syringe, - Luer - Activated Valve, - Dilator	Similar, the 074 and 087 Neurovascular Access System includes a Dilator, like the secondary predicate.

VII. PERFORMANCE DATA

The results of verification and validation testing conducted on the Neurovascular Access System Family demonstrate that it performs as designed and is substantially equivalent to the predicate. A summary of the tests performed is provided in the table below:

Test Name	Objective	Test Method / Standard or Guidance	Result
Visual Surface Requirements	To demonstrate that the device meets the visual surface requirements.	ISO 10555-1 2013, Section 4.4	Pass
Dimensional Verification	To demonstrate that the device meets the dimensional requirements.	ISO 10555-1 2013, Section 4.5	Pass
Liquid Leakage Under Pressure	To demonstrate that the device passes the liquid leakage under pressure test.	ISO 10555-1 2013, Section 4.7.1, Annex C	Pass
Hub Aspiration Air Leakage	To demonstrate that the device passes the hub aspiration air leakage test.	ISO 10555-1 2013, Section 4.7.2, Annex D	Pass
Simulated Use and Usability	To demonstrate that the device passes testing specified in the simulated use test protocol. Simulated use testing includes usability assessment with multiple physicians.	FDA guidance: "Peripheral Percutaneous Transluminal Angioplasty (PTA) and Specialty Catheters - Premarket Notification (510(k)) Submissions", April 2023	Pass

Test Name	Objective	Test Method / Standard or Guidance	Result
Flex Fatigue	To demonstrate that the device passes the flex fatigue test.	FDA guidance: "Peripheral Percutaneous Transluminal Angioplasty (PTA) and Specialty Catheters - Premarket Notification (510(k)) Submissions", April 2023	Pass
Torque Test	To demonstrate the torque strength of the device.	FDA guidance: "Peripheral Percutaneous Transluminal Angioplasty (PTA) and Specialty Catheters - Premarket Notification (510(k)) Submissions" April 2023	Pass
Tip Deflection	To demonstrate that the tip deflection is comparable to the predicate device.	FDA Guidance: "Peripheral Percutaneous Transluminal Angioplasty (PTA) and Specialty Catheters - Premarket Notification (510(k)) Submissions" April 2023	Pass
Device Removal Forces	To demonstrate that the removal forces are comparable to the predicate device.	FDA Guidance: "Peripheral Percutaneous Transluminal Angioplasty (PTA) and Specialty Catheters - Premarket Notification (510(k)) Submissions" April 2023	Pass
Peak Tensile Strength Testing	To demonstrate that the device passes the peak tensile strength testing including all bonds and joints.	ISO 10555-1 2013, Section 4.6, Annex B	Pass
Flow Rate	To demonstrate that the flow rate is comparable to the predicate device.	ISO 10555-1 2013: Section 4.9	Pass
Corrosion Resistance	To demonstrate that the device has no visual evidence of corrosion.	ISO 10555-1 2013, Section 4.5, Annex A	Pass
Radiopacity	To demonstrate that the distal marker band is clearly visible under typical fluoroscopic imaging conditions.	ISO 10555-1 2013, Section 4.2 ASTM F640-12	Pass
Kink Resistance	To demonstrate that shaft kink resistance is comparable to the predicate device and clinically relevant for the intended anatomical locations for use.	FDA Guidance: "Peripheral Percutaneous Transluminal Angioplasty (PTA) and Specialty Catheters - Premarket Notification (510(k)) Submissions"	Pass

Test Name	Objective	Test Method / Standard or Guidance	Result
Particulates and Coating Integrity	To demonstrate the quantity and size of particles generated during simulated use are comparable to the predicates and reference devices.	FDA Guidance: "Peripheral Percutaneous Transluminal Angioplasty (PTA) and Specialty Catheters - Premarket Notification (510(k)) Submissions"	Pass
Dynamic Burst	To demonstrate that the device withstands dynamic burst strength.	ISO 10555-1 2103, Annex G	Pass
Static Burst	To demonstrate that the device passes static burst pressure as specified in the test protocol.	ISO 10555-1 2013, Section F	Pass
Shelf Life	Repeated bench tests after accelerated aging to demonstrate that the device performance is maintained over the proposed shelf-life (6 months).	ASTM D4332-22 ASTM D4169-22 ASTM F1980-21 ASTM F1886 / F1866M-16 ASTM 2096-11 (2019) ASTM F88/F88M:21	Pass

VIII. BIOCOMPATIBILITY

The subject Neurovascular Access System Family is categorized as an externally communicating device contacting circulating blood for a limited (≤ 24 hours) duration in accordance with ISO 10993-1. The following testing supports biocompatibility and substantial equivalence of the subject device.

Test Name	Reference Standard	Results	Results
Cytotoxicity	ISO 10993-5	No reactivity was observed with the test article at 24 and 48 hours.	Non-cytotoxic
Sensitization	ISO10993-10	The test article extracts showed no evidence of delayed dermal contact sensitization in the guinea pig maximization test.	Non-sensitizing
Intracutaneous Reactivity	ISO 10993-23	The scores from test article extracts were 0 from the saline extract and <1.0 from the sesame seed oil extract.	Non-irritant
Acute Systemic Toxicity	ISO 10993-11	There was no mortality or evidence of systemic toxicity from the extracts injected into mice. Each test article extract met the requirements of the study.	Non-toxic
Material Mediated Pyrogenicity	ISO 10993-11	No rabbit temperature rise ≥ 0.5 °C.	Non-pyrogenic

Test Name	Reference Standard	Results	Results
Hemolysis - Direct Contact and Extract Method	ISO 10993-4	The mean blank corrected % hemolysis above the negative control of the test article was < 2% for the extract method.	Non-hemolytic
Complement Activation	ISO 10993-4	Results within acceptable range as compared to the controls.	Not a Sc5b-9 complement activator
Thrombogenicity	ISO 10993-4	No adverse effects or clinical signs during test period and no thrombus score ≥ 2 for either test or control device in *in vivo* thrombogenicity study. Performed similar to comparator and negative controls in Partial Thromboplastin Time and Platelet and Leukocyte Counts testing.	Non-thrombogenic

IX. STERILITY

The subject Neurovascular Access System Family is sterilized with ethylene oxide (EO). The sterilization process has been validated in accordance with ISO 11135:2014 to achieve a sterility assurance level (SAL) of $1x\ 10^{-6}$. EO and Ethylene Chlorohydrin (ECH) residuals were below the limits specified in ISO 10993 7:2008. Bacterial Endotoxin Levels were below the level of 2.15 endotoxin units (EU)/device in accordance with FDA's sterility guidance. Both baseline and accelerated shelf-life testing were conducted demonstrating the device will perform as intended to support the proposed 6-month shelf-life.

X. ANIMAL STUDY

Animal testing was not deemed necessary to support the substantial equivalence of the Neurovascular Access System Family.

XI. Clinical

Clinical testing was not deemed necessary to support the substantial equivalence of the Neurovascular Access System Family.

XII. CONCLUSION

The Neurovascular Access System Family has the same intended use and similar indications for use as the primary predicate and secondary predicate. The technological characteristics of the subject device are similar to the predicate device. The differences in technological characteristics do not raise new questions of safety and effectiveness. The performance testing supports that the subject Neurovascular Access System Family is substantially equivalent to the predicate.