June 22, 2023

Q'Apel Medical, Inc.
Kim Ky
Manager, Regulatory Affairs
4245 Technology Drive
Fremont, California 94538

Re: K230322
Trade/Device Name: SelectFlex Neurovascular Access System Family
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous Catheter
Regulatory Class: Class II
Product Code: QJP, DQY
Dated: May 23, 2023
Received: May 23, 2023

Dear Kim Ky:

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 (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 located 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.

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 803) for devices or postmarketing safety reporting (21 CFR 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 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*

K230322

Device Name
SelectFlex Neurovascular Access System Family

Indications for Use *(Describe)*
The SelectFlex Neurovascular Access System Family is indicated for the introduction of interventional devices into the peripheral and neurovasculature.

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
As required by 21 CFR 807.92

Applicant:
Submitter's Name: Q'Apel Medical Inc.
Address: 4245 Technology Drive
Fremont, CA 94538

Telephone: 510-738-6255
Fax: 510-738-6256

Contact Person:
Contact Person: Kim Ky
Title: Manager, Regulatory Affairs
Telephone: 510-828-4757

Date Prepared: June 21, 2023

Device Trade name: SelectFlex Neurovascular Access System Family

Classification: Class II

Product Codes: QJP, DQY

Regulation Number: 21 CFR 870.1250

Classification Name: Catheter, Percutaneous, Neurovasculature

Predicate Device: Benchmark Intracranial Access System (K212838)

Reference Device: SelectFlex Neurovascular Access System Family (K211893)

Indications for Use:
The SelectFlex Neurovascular Access System Family is indicated for the introduction of interventional devices into the peripheral and neurovasculature.

Device Description:
The subject SelectFlex Neurovascular Access System Family is a line extension to expand the previously cleared device (K211893) by offering a new SelectFlex III 064 Neurovascular Access Catheter with a diameter of 6F, a 6F dilator, an introducer sheath, and a 4.5F Access Tool that can be used with the catheter to access the desired anatomy. The 4.5F Access Tool is an accessory provided with the SelectFlex III 064 Neurovascular Access Catheter and is packaged in the same sterile pouch with the SelectFlex III 064 Neurovascular Access Catheter and accessories as part of the SelectFlex Neurovascular Access System Family.

Comparison of Technological Characteristics with the Predicate and Reference Devices

The subject expanded SelectFlex Neurovascular Access System Family incorporates similar design, packaging, fundamental technology, manufacturing processes, sterilization process, and intended use as the predicate device (K212838) and reference device (K211893).

Device Comparison Table				
Feature	**Subject Device**	**Predicate Device**	**Reference Device**	**Comparison**
Device Name	**SelectFlex Neurovascular Access System Family**	**Benchmark Intracranial Access System**	**SelectFlex Neurovascular Access System Family**	N/A
510(k) Number	K230322	K212838	K211893	N/A
Classification	Class II	Class II	Class II	Same
Product Codes	QJP, DQY	QJP, DQY	QJP, DQY	Same
Regulation Number	870.1250	870.1250	870.1250	Same
Indications for Use	The SelectFlex Neurovascular Access System Family is indicated for the introduction of interventional devices into the peripheral and neurovasculature.	The Benchmark Intracranial Access System is indicated for the introduction of interventional devices into the peripheral, coronary, and neuro vasculature.	The SelectFlex Neurovascular Access System Family is indicated for the introduction of interventional devices into the peripheral and neurovasculature.	Same
Materials	Commonly used medical-grade plastics, stainless steel, nitinol.	Commonly used medical grade plastics and stainless steel.	Commonly used medical-grade plastics, stainless steel, nitinol.	Similar, the differences do not raise new questions regarding safety and effectiveness.
Outer Diameter (OD)	6F catheter: 0.083 in	0.081 – 0.083 in	7F catheter: 0.095 in	Similar, the difference does not raise new questions regarding safety and effectiveness.
Inner Diameter (ID)	6F catheter: 0.064 in Min	0.070 in Min	7F catheter: 0.072 in Min	Similar, the difference does not raise new questions regarding safety and effectiveness.
Effective length	95 and 105 cm	95 and 105 cm	95, 105, and 115 cm	Same
Tip Shape	Straight	Straight & Multi-Purpose	Straight	Same as reference device
Injection Port	Yes	Yes	Yes	Same
Radiopaque	Yes	Yes	Yes	Same

Device Comparison Table				
Feature	**Subject Device**	**Predicate Device**	**Reference Device**	**Comparison**
Device Name	**SelectFlex Neurovascular Access System Family**	**Benchmark Intracranial Access System**	**SelectFlex Neurovascular Access System Family**	N/A
Coating length	30 cm	10 cm	11.5 and 30 cm	Same as reference device
Shaft Reinforcement	Stainless steel reinforced shaft	Stainless steel reinforced shaft	Stainless steel reinforced shaft	Same
Variable Stiffness Mechanism	Variable durometer catheter shaft construction to deliver a flexible distal tip and transition to a stiffer proximal section; ten transition segments between the distal tip and proximal shaft. & Two user-selectable variable stiffness modes of the distal 10 cm by application of fluid into the distal scaffold chamber of the catheter wall. Fluid pressure enables the more flexible tracking mode; fluid withdrawal switches to a less flexible and more supportive mode.	Variable durometer catheter shaft construction.	Variable durometer catheter shaft construction to deliver a flexible distal tip and transition to a stiffer proximal section; ten transition segments between the distal tip and proximal shaft. & Two user-selectable variable stiffness modes of the distal 10 cm by application of fluid into the distal scaffold chamber of the catheter wall. Fluid pressure enables the more flexible tracking mode; fluid withdrawal switches to a less flexible and more supportive mode.	Same as reference device
Accessories Supplied	7F Introducer Sheath	N/A	7F Introducer Sheath	Same as reference device
	3 cc syringe	N/A	3 cc syringe	Same as reference device
	Luer Activated Valve	N/A	Luer Activated Valve	Same as reference device

Device Comparison Table				
Feature	**Subject Device**	**Predicate Device**	**Reference Device**	**Comparison**
Device Name	**SelectFlex Neurovascular Access System Family**	**Benchmark Intracranial Access System**	**SelectFlex Neurovascular Access System Family**	N/A
	Dilator Effective Length: 105 and 115 cm ID: 0.039 ± 0.001 in OD: 0.060 ± 0.001 in Tip-Taper Distance: 0.394 in Tip-Tapered OD: 0.14 cm Material: Hub: CS 00542, Winged Armadillo Dilator Hub Shaft: Pebax 7233 Shaft Colorant: 1.25% Max Foster MediBatch Slate Grey UMBXXX031616C1	N/A	**Dilator** Effective Length: 105, 115, 125 cm ID: 0.039 ± 0.001 in OD: 0.068 ± 0.001 in Tip-Taper Distance: 0.591 in Tip-Tapered OD: 0.14 cm Material: Hub: CS 00542, Winged Armadillo Dilator Hub Shaft: Pebax 7233 Shaft Colorant: 1.25% Max Foster MediBatch Slate Grey UMBXXX031616 C1	Similar to reference device
	4.5F Access Tool Effective Length: 130 and 140 cm ID: 0.038 in Min OD: 4.5F (0.061 in Max) Tip Shape: Simmons Material: Commonly used medical grade plastics & stainless steel	**5F Select Catheter** Effective Length: 123 and 131.5 cm ID: 0.043 in Min OD: 5F (0.069 in Max) Tip Shapes: Berenstein, H1, and Simmons Material: Commonly used medical grade plastics & stainless steel	N/A	Similar to predicate device
Guidewire Compatibility	0.035 - 0.038 in	0.035 - 0.038 in	0.035 - 0.038 in	Same
How Supplied	Sterile, single-use	Sterile, single-use	Sterile, single-use	Same
Sterilization method	Ethylene oxide (EtO)	EtO	EtO	Same

Device Comparison Table				
Feature	**Subject Device**	**Predicate Device**	**Reference Device**	**Comparison**
Device Name	**SelectFlex Neurovascular Access System Family**	**Benchmark Intracranial Access System**	**SelectFlex Neurovascular Access System Family**	N/A
Sterility Assurance Level	10^{-6}	10^{-6}	10^{-6}	Same
Shelf-Life	6 months	36 months	36 months	A 6-month shelf life was Validated for the subject device.

Nonclinical Performance Data:

The following nonclinical performance testing was conducted to support the determination of substantial equivalence.

Performance Testing Summary:

Bench testing was performed to evaluate the physical integrity, functionality, and performance of the SelectFlex Neurovascular Access System Family:

Test Name	Goal	Reference Standard or Guidance	Result
Visual Surface Requirements (SelectFlex III 064 Neurovascular Access Catheter, 6F Dilator, 4.5F Access Tool)	To demonstrate that the device meets the visual surface requirements.	ISO 10555-1 2013: Intravascular catheters – Sterile and single-use catheters – Part 1: General requirements	Pass All samples met the predetermined acceptance criteria.
Dimensional Verification (SelectFlex III 064 Neurovascular Access Catheter, 6F Dilator, 4.5F Access Tool)	To demonstrate that the device meets the dimensional requirements.	ISO 10555-1 2013: Intravascular catheters – Sterile and single-use catheters – Part 1: General requirements	Pass All samples met the predetermined acceptance criteria.
Liquid Leakage Under Pressure (SelectFlex III 064 Neurovascular Access Catheter)	To demonstrate that the device passes the liquid leakage under pressure test.	ISO 10555-1 2013, Section 4.7.1, Annex C	Pass All samples met the predetermined acceptance criteria.
Hub Aspiration Air Leakage (SelectFlex III 064 Neurovascular Access Catheter)	To demonstrate that the device passes the hub aspiration air leakage test.	ISO 10555-1 2013, Section 4.7.2, Annex D	Pass All samples met the predetermined acceptance criteria.
Simulated Use/Usability (SelectFlex III 064 Neurovascular Access Catheter, 6F Dilator, 4.5F Access Tool)	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: "Coronary, Peripheral, and Neurovascular Guidewires – Performance Tests and Recommended Labeling"	Pass All samples met the predetermined acceptance criteria.
Flex Fatigue (SelectFlex III 064 Neurovascular Access Catheter, 6F Dilator, 4.5F Access Tool)	To demonstrate that the device passes the flex fatigue test.	FDA guidance: "Coronary, Peripheral, and Neurovascular Guidewires – Performance Tests and Recommended Labeling"	Pass All samples met the predetermined acceptance criteria.
Inflation Fatigue	To demonstrate that	ISO 10555-1 2013,	Pass

Test Name	Goal	Reference Standard or Guidance	Result
(SelectFlex III 064 Neurovascular Access Catheter)	the device passes the inflation fatigue test.	Section 4.7.1 – 20 inflation cycles	All samples met the predetermined acceptance criteria.
Burst Volume (SelectFlex III 064 Neurovascular Access Catheter)	To demonstrate that the device passes the burst volume test – tested to 2x the inflation volume.	ISO 10555-1 2013: Intravascular catheters - Sterile and single-use catheters - Part 1: General requirements	Pass All samples met the predetermined acceptance criteria.
Torque Test (SelectFlex III 064 Neurovascular Access Catheter, 4.5F Access Tool)	To demonstrate the device's ability to rotate 720 degrees (2 full revolutions) at the proximal end.	ISO 10555-1 2013: Intravascular catheters - Sterile and single-use catheters - Part 1: General requirements	Pass All samples met the predetermined acceptance criteria.
Tip Deflection (SelectFlex III 064 Neurovascular Access Catheter)	To demonstrate that the tip deflection is comparable to the predicate device.	FDA Guidance: "Coronary, Peripheral, and Neurovascular Guidewires – Performance Tests and Recommended Labeling"	Pass All samples met the predetermined acceptance criteria.
Device Removal in Support and Tracking Modes (SelectFlex III 064 Neurovascular Access Catheter)	To demonstrate that the forces in both support and tracking modes are comparable to the predicate device.	FDA Guidance: "Coronary, Peripheral, and Neurovascular Guidewires – Performance Tests and Recommended Labeling"	Pass All samples met the predetermined acceptance criteria.
Peak Tensile Testing (SelectFlex III 064 Neurovascular Access Catheter, 6F Dilator, 4.5F Access Tool)	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 All samples met the predetermined acceptance criteria.
Flow Rate (SelectFlex III 064 Neurovascular Access Catheter)	To demonstrate that the flow rate is comparable to the predicate device.	ISO 10555-1 2013: Intravascular catheters - Sterile and single-use catheters - Part 1: General requirements	Pass All samples met the predetermined acceptance criteria.
Corrosion Resistance (SelectFlex III 064 Neurovascular Access Catheter, 4.5F Access Tool)	To demonstrate that the device has no visual evidence of corrosion.	ISO 10555-1 2013, Section 4.5, Annex A	Pass All samples met the predetermined acceptance criteria.
Radiopacity (SelectFlex III 064 Neurovascular Access Catheter, 4.5F Access Tool)	To demonstrate that the marker band is positioned at the distal tip of the catheter and is clearly visible under typical fluoroscopic imaging conditions.	I.SO 10555-1 2013: Intravascular catheters - Sterile and single-use catheters - Part 1: General requirements	Pass All samples met the predetermined acceptance criteria.

Test Name	Goal	Reference Standard or Guidance	Result
Particulates, Coating Integrity, Lubricity, Durability (SelectFlex III 064 Neurovascular Access Catheter)	To demonstrate the quantity and size of particles generated during simulated use are comparable to the predicate and reference devices.	1. AAMI TIR42:10 Evaluation of particulates associated with vascular medical devices 2. Intravascular Catheters, Wires, and Delivery Systems with Lubricious Coatings – Labeling Considerations, issued on October 10, 2019.	Pass All samples met the predetermined acceptance criteria.
Static Burst (SelectFlex III 064 Neurovascular Access Catheter, 4.5F Access Tool)	To demonstrate that the device passes static burst as specified in the test protocol.	ISO 10555-1 2013: Intravascular catheters - Sterile and single-use catheters - Part 1: General requirements	Pass All samples met the predetermined acceptance criteria.
Shelf Life (SelectFlex III 064 Neurovascular Access Catheter, 6F Dilator, 4.5F Access Tool)	To demonstrate that the device performance is maintained over the proposed shelf-life (6 months).	ASTM D4332, Standard Practice for Conditioning Containers, Packages, or Packaging Components for Testing	Pass All samples met the predetermined acceptance criteria.

The results of these tests provide reasonable assurance that the subject device has been designed and tested to assure conformance to the requirements for its intended use. No new safety or performance issues were raised during the testing.

Biocompatibility Testing:

The subject SelectFlex III 064 Neurovascular Access Catheter is categorized as limited exposure (< 24 hours), externally communicating device with circulating blood contact in accordance with ISO 10993-1. Q'Apel has conducted biocompatibility testing per ISO 10993-1 on the predicate device which supports the biocompatibility of the subject catheter.

Additional biocompatibility testing was performed on the 4.5F Access Tool:

Test Name	Reference Standard	Results	Conclusion
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 0 from the sesame seed oil extract.	Non-irritant

Test Name	Reference Standard	Results	Conclusion
Acute Systemic Toxicity	ISO 10993-11	No abnormal clinical signs indicative of toxicity were observed for 72 hours. All animals were alive at the end of 72 hours and body weight changes were within acceptable parameters.	Non-toxic
Material Mediated Pyrogenicity	ISO 10993-11	No rabbit temperature rise ≥ 0.5 °C.	Non-pyrogenic
Hemolysis - Direct Contact and Extract Method	ISO 10993-4	Blank corrected hemolytic index: 0.15, 0.13.	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.	Non-thrombogenic

Animal Study:

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

Clinical:

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

Conclusion:

The SelectFlex Neurovascular Access System Family has the same intended use and indications for use as the predicate Benchmark Intracranial Access System (K212838). 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 subject SelectFlex Neurovascular Access System Family is substantially equivalent to the predicate device, Benchmark Intracranial Access System.