August 5, 2021

Q'Apel Medical Inc
% Michele Lucey
President
Lakeshore Medical Device Consulting LLC
128 Blye Hill Landing
Newbury, New Hampshire 03255

Re: K211893
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: July 6, 2021
Received: July 7, 2021

Dear Michele Lucey:

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, 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)*
K211893

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.

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K211893

SPECIAL 510(k) SUMMARY
As required by 21 CFR 807.92

Submitter Information:

Submitter's Name:	Q'Apel Medical Inc
Address:	46708 Lakeview Blvd
	Fremont CA 94538
Telephone:	510-738-6255
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Contact Person:	Michele Lucey
Telephone:	603-748-1374

Date Prepared:	August 4, 2021
Device Trade Name:	SelectFlex Neurovascular Access System Family
Classification:	Class II
Product Code(s):	QJP, DQY
Regulation Number(s):	870.1250
Classification Name	Percutaneous Catheter
Predicate Devices:	SelectFlex 072 Neurovascular Access System K191664

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 SelectFlex Neurovascular Access System Family consists of sterile, single-use intravascular catheters used to facilitate access to target vasculature during interventional procedures. The system is composed of a SelectFlex Neurovascular Access Catheter, a 3cc Mode Control Syringe, a 7Fr Peel Away Introducer, Luer Activated Valve and a Dilator (only for versions with a Long Hydrophilic coating to ease dermal entry). The SelectFlex Neurovascular Access Catheter comes in usable lengths of 95, 105 or 115cm. The SelectFlex Neurovascular Access Catheter has variable stiffness along its length and has a dual mode stiffness mechanism on the distal portion of the catheter that is activated by the user allowing the device to transition between tracking and support modes. The distal end of the SelectFlex Neurovascular Access Catheter comes in two options of a short hydrophilic coating length of 11.5cm or a long hydrophilic coating length of 30cm.

Comparison of Technological Characteristics

The SelectFlex Neurovascular Access System Family incorporates substantially equivalent design, packaging, fundamental technology, manufacturing processes, sterilization process and intended use as those contained in the SelectFlex 072 Neurovascular Access System (K191664). The following table provides a comparison of the subject device to the predicate device:

Comparison Table to Demonstrate Substantial Equivalence			
Feature	**Subject Device**	**Predicate Device**	**Comparison**
	SelectFlex Neurovascular Access System Family	SelectFlex 072 Neurovascular Access System	
Regulatory Clearance/Approval Reference	Pending	K191664	NA
FDA Classification	Class II	Class II	Same
Product Code(s)	QJP, DQY	DQY	Same
Regulation Number	870.1250	870.1250	Same
Material	Commonly used medical grade plastics, stainless steel, nitinol	Commonly used medical grade plastics, stainless steel, nitinol	Similar, difference does not raise new questions regarding safety and efficacy
Outer Diameter	.095-in	.095-in	Same
Inner dimension	.072-in	.072-in	Same
Fr Designation	7 Fr	7 Fr	Same
Effective length	95, 105, and 115cm	105cm	Similar, additional lengths are consistent with catheters of this type, this difference does not raise new questions regarding safety of effectiveness
Tip Shape	Straight	Straight	Same
Injection Port	Yes	Yes	Same
Radiopaque	Distal Tip has a radiopaque marker band, stainless steel reinforcement and nitinol scaffold in the catheter shaft renders the shaft visible on fluoroscopy	Distal Tip has a radiopaque marker band, stainless steel reinforcement and nitinol scaffold in the catheter shaft renders the shaft visible on fluoroscopy	Same

Comparison Table to Demonstrate Substantial Equivalence			
Feature	**Subject Device**	**Predicate Device**	**Comparison**
	SelectFlex Neurovascular Access System Family	SelectFlex 072 Neurovascular Access System	
Coating	Hydrophilic Coating – Distal Portion 11.5cm and 30cm	Hydrophilic Coating – Distal Portion 11.5cm	Similar, difference does not raise new questions regarding safety and effectiveness
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 10cm 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 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 10cm 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

Comparison Table to Demonstrate Substantial Equivalence			
Feature	**Subject Device**	**Predicate Device**	**Comparison**
	SelectFlex Neurovascular Access System Family	SelectFlex 072 Neurovascular Access System	
Distal End Segment Length	17, 22, and 27cm	17cm	Similar, difference does not raise new questions regarding safety and effectiveness
Tip Stiffness	0.12 N (tracking and support mode)	0.12 N (tracking and support mode)	Same
Accessories Supplied	7 Fr Introducer Sheath 3cc syringe Luer Activated Valve Dilator (only included with catheters that have a Long Hydrophilic Coating)	7 Fr Introducer Sheath 3cc syringe Hub Extension Line	Similar, difference does not raise new questions regarding safety and effectiveness
Guidewire Compatibility	0.035-0.038-in	0.035-0.038-in	Same
How Supplied	Sterile, single use	Sterile, single use	Same
Sterilization Method	EtO	EtO	Same
Sterility Assurance Level	10^{-6}	10^{-6}	Same

Substantial Equivalence:

This summary demonstrates that the SelectFlex Neurovascular Access System Family and the predicate device have the same intended use, similar technological characteristics, materials, and principles of operation. It can therefore be concluded that the SelectFlex Neurovascular Access System Family is substantially equivalent to the predicate device.

Nonclinical Performance Data:

Determination of substantial equivalence is based on an assessment of non-clinical performance bench test data.

Bench Testing:

Bench testing was performed to evaluate physical integrity, functionality, and performance of the SelectFlex Neurovascular Access System Family. Performance data includes dimensional verification, delivery and removal under simulated use conditions, bond tensile strength, and compatibility with interface devices. A summary of all tests performed is provided in the following table:

Test Description	Test Method	Results
Visual Surface Requirements (catheter and dilator)	Visual inspection of catheter surfaces	PASS All samples met the pre-determined acceptance criteria
Dimensional Verification (catheter and dilator)	Device dimensions were measured to confirm conformance to the product specification	PASS All samples met the pre-determined acceptance criteria
Simulated Use/Usability	Device preparation, delivery, access, was evaluated in a challenging neurovascular model. Simulated use testing includes a usability assessment with multiple physicians	PASS All samples met the pre-determined acceptance criteria
Flexion Fatigue	Tested per ISO 10555-1: 2013 for Flexural Fatigue	PASS All samples met the pre-determined acceptance criteria
Inflation Fatigue	Tested per ISO 10555-1: 2013 for Inflation Fatigue – 20 inflation cycles	PASS All samples met the pre-determined acceptance criteria
Burst Volume	Tested per ISO 10555-1: 2013 for Inflation Fatigue – tested to 2x the inflation volume	PASS All samples met the pre-determined acceptance criteria
ISO 80369-7: Small Bore Connectors for Hypodermic Applications	Tested per ISO 80369-7, dimensional, leakage by pressure decay, freedom from air leakage, positive pressure liquid leakage, sub-atmospheric pressure air leakage, stress cracking, resistance to separation from axial load, resistance to separation from unscrewing, resistance to overriding	PASS All samples met the pre-determined acceptance criteria

Test Description	Test Method	Results
Particulate Count	Effluent tested per AAMI TIR42, USP 788 using multiple insertion and withdrawal cycles	PASS All samples met the pre-determined acceptance criteria
Peak Tensile Testing (catheter and dilator)	Tested per ISO 10555-1 for tensile strength including all bonds/joints	PASS All samples met the pre-determined acceptance criteria

The results of these tests provide reasonable assurance that the 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; therefore, this device is substantially equivalent to the predicate device.

Biocompatibility:

The subject device is primarily comprised of the same materials used in the predicate device. Where there are minor differences, biocompatibility has been demonstrated through company testing of other devices with the same tissue contact categorization. No additional biocompatibility testing was performed.

Conclusion:

Based on the indications for use, technological characteristics, and performance testing, the SelectFlex Neurovascular Access System Family has been shown to be appropriate for its intended use and is considered to be substantially equivalent to the SelectFlex 072 Neurovascular Access System, K191664.