August 30, 2019

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

Re: K191664
Trade/Device Name: SelectFlex 072 Neurovascular Access System
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous catheter
Regulatory Class: Class II
Product Code: DQY
Dated: July 30, 2019
Received: August 1, 2019

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,

for Xiaolin Zheng, 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K191664

Device Name
SelectFlex 072 Neurovascular Access System

Indications for Use *(Describe)*
The SelectFlex 072 Neurovascular Access System 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.

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

Submitter Information:

Submitter's Name:	Q'Apel Medical LLC
Address:	330 Wilshire Boulevard
	Santa Monica CA 90401
Telephone:	310-395-3950
Fax:	310-395-1122
Contact Person:	Michele Lucey
Telephone:	603-748-1374

Date Prepared:	August 30, 2019
Device Trade Name:	SelectFlex 072 Neurovascular Access System
Classification:	Class II
Product Code(s):	DQY
Regulation Number(s):	870.1250
Classification Name	Percutaneous Catheter
Predicate Devices:	SelectFlex 072 Neurovascular Access System K181000

Indication for Use:
The SelectFlex 072 Neurovascular Access System is indicated for the introduction of interventional devices into the peripheral and neurovasculature.

Device Description

The SelectFlex 072 Neurovascular Access System is a sterile, single-use intravascular catheter used to facilitate access to target vasculature during interventional procedures. The system is composed of a the SelectFlex 072 Catheter, a 3cc Inflation Syringe, a 7Fr Peel Away Introducer, and Hub Extension Line. The 072 SelectFlex Catheter has a usable length of 105cm. The SelectFlex 072 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 072 Catheter has a hydrophilic coating.

Comparison of Technological characteristics

The 072 Neurovascular Access System incorporates substantially equivalent design, packaging, fundamental technology, manufacturing processes, sterilization process and intended use as those contained in the 072 Neurovascular Access System (K181000). 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 072 Neurovascular Access System	SelectFlex 072 Neurovascular Access System	
Regulatory Clearance/	Pending	K181000	NA

Comparison Table to Demonstrate Substantial Equivalence			
Feature	**Subject Device**	**Predicate Device**	**Comparison**
	SelectFlex 072 Neurovascular Access System	SelectFlex 072 Neurovascular Access System	
Approval Reference			
FDA Classification	Class II	Class II	Same
Product Code(s)	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	105cm	105cm	Same
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
Coating	Hydrophilic Coating – Distal Portion (11.5cm)	Hydrophilic Coating – Distal Portion (10cm)	Similar, difference does not raise new questions regarding safety and efficacy
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	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. &	Same

Comparison Table to Demonstrate Substantial Equivalence			
Feature	**Subject Device**	**Predicate Device**	**Comparison**
	SelectFlex 072 Neurovascular Access System	SelectFlex 072 Neurovascular Access System	
	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.	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.	
Tip Stiffness	0.12 N (tracking and support mode)	Ranges from 0.12-0.16 N (tracking and support mode)	Similar, difference does not raise new questions regarding safety and efficacy
Accessories Supplied	7 Fr Introducer Sheath 3cc syringe Hub Extension Line	7 Fr Introducer Sheath 3cc syringe	Similar, difference does not raise new questions regarding safety and efficacy
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 072 Neurovascular Access System and the predicate device have the same intended use, similar technological characteristics, materials, and principals of operation. It can therefore be concluded that the SelectFlex 072 Neurovascular Access System 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 072 Neurovascular Access System. Performance data includes dimensional, delivery and removal under simulated use conditions, bond tensile strength, tip flexibility, hub aspiration and leakage, liquid leakage under pressure, torque, biocompatibility and compatibility with interface devices. A summary of all tests performed is provided in the following table:

Test Description	Test Method	Results
Packaging Integrity (sterile barrier)	Tested per ISO 11607-1 and -2	PASS All samples met the pre-determined acceptance criteria
Visual Surface Requirements	Visual inspection of catheter surfaces	PASS All samples met the pre-determined acceptance criteria
Dimensional Verification	Device dimensions were measured to confirm conformance to the product specification	PASS All samples met the pre-determined acceptance criteria
Liquid Leakage Under Pressure	Tested per ISO 10555-1:2013 Annex C	PASS All samples met the pre-determined acceptance criteria
Hub Aspiration Air Leakage	Tested per ISO 10555-1 2013 for Hub Aspiration Air Leakage	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
Flex Fatigue	Tested per ISO 10555-1: 2013 for Flexural Fatigue	PASS All samples met the pre-determined acceptance criteria
Tip Deflection	The amount of tip deflection under load was evaluated and compared to the predicate device	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

Test Description	Test Method	Results
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
Torque Test	Tested per ISO 10555-1: 2013 for Torque Testing	PASS All samples met the pre-determined acceptance criteria
Flow Rate	Tested per ISO 10555-1: 2013 for Flow rate compared to the predicate device	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
Corrosion Resistance	Tested per ISO 10555-1 Annex A for corrosion resistance	PASS All samples met the pre-determined acceptance criteria
Particulate Count	Effluent tested per AAMI TIR42, USP 788 using multiple insertion and withdrawal cycles	PASS All samples met the pre-determined acceptance criteria
Coating Integrity, Lubricity, Durability	Tested in consideration of FDA CTQ for Hydrophilic Coated vascular catheters	PASS All samples met the pre-determined acceptance criteria
Peak Tensile Testing	Tested per ISO 10555-1 for tensile strength including all bonds/joints	PASS All samples met the pre-determined acceptance criteria
Device Removal in Support and Tracking Modes	Removal force in both modes was compared to a reference device	PASS All samples met the pre-determined acceptance criteria
Radiopacity	Radiopacity was evaluated during simulated use testing confirming visualization under fluoroscopy	PASS All samples met the pre-determined acceptance criteria

Test Description	Test Method	Results
Shelf Life	Accelerated aging studies were completed to confirm the stability of the product and package. All testing noted above was performed on aged product to support the shelf life claim	PASS All samples met the pre-determined acceptance criteria

The results of these tests provide reasonable assurance that the proposed 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 considered to be substantially equivalent to the predicate device.

Biocompatibility Testing Summary:

Categorized as Externally Communicating Device, Circulating Blood, Limited Contact (≤ 24 hours), per ISO 10993-1, the following testing was conducted and results were acceptable:

Test Name	Test Method	Results
Cytotoxicity	Tested in accordance with ISO 10993-5, Biological Evaluation of Medical Devices – Part 5: Tests for *in vitro* toxicity, Neutral Red Uptake Method	Pass Noncytotoxic according to the predetermined acceptance criteria
Intracutaneous Irritation	Tested in accordance with ISO 10993-10, Biological Evaluation of Medical Devices – Part 10: Tests for Irritation and Skin Sensitization	Pass Test requirements for intracutaneous reactivity were met according to the predetermined acceptance criteria
Sensitization	Tested in accordance with ISO 10993-10, Biological Evaluation of Medical Devices – Part 10 Tests for Irritation and Skin Sensitization, Kligman Maximization Test	Pass did not elicit a sensitization response according to the predetermined acceptance criteria
Systemic Toxicity	Tested in accordance with ISO 10993-11, Biological Evaluation of Medical Devices – Part 11: Tests for Systemic Toxicity	Pass Test requirements for systemic toxicity were met according to the predetermined acceptance criteria
Material Mediated Pyrogenicity	Tested in accordance with ISO 10993-11, Biological Evaluation of Medical Devices – Part 11: Tests for Systemic Toxicity and USP 40 <151> Pyrogen Test	Pass Nonpyrogenic, met the predetermined acceptance criteria
Hemolysis	Tested in accordance with ASTM F756-17, Standard Practice for Assessment of Hemolytic Properties of Materials and ISO 10993-4, Biological Evaluation of Medical Devices – Part 4: Selection of Tests for Interactions with Blood, Tests for Hemolytic Properties, Direct and Indirect Methods	Pass Non-hemolytic, met the predetermined acceptance criteria
In Vitro Hemocompatibility	Tested in accordance with ISO 10993-4, Biological Evaluation of Medical Devices – Part 4: Selection of Tests for Interactions with Blood, Hemocompatibility, Direct Contact Method	Pass Not expected to result in adverse effects *in vivo,* met the predetermined acceptance criteria
Complement Activation	Tested in accordance with ISO 10993-4, Biological Evaluation of Medical Devices – Part 4: Selection of Tests for Interactions with Blood, SC5b-9 Complement Activation	Pass Does not activate the complement system, met the predetermined acceptance criteria

Un-activated Partial Thromboplastin Time	Tested in accordance with ISO 10994-4, Biological Evaluation of Medical Devices – Part 4: Selection of Tests for Interactions with Blood and ASTM F2382-04, Standard Test Method for Assessment of Intravascular Medical Device Materials on Partial Thromboplastin Time (UPTT)	Pass Does not have an effect on coagulation of human plasma, met the predetermined acceptance criteria
Thrombogenicity	Tested in accordance with ISO 10994-4, Biological Evaluation of Medical Devices – Part 4: Selection of Tests for Interactions with Blood	Pass Demonstrates similar thromboresistance characteristics as the control device, met the predetermined acceptance criteria
Bacterial Endotoxin	Testing was performed in accordance with USP 40, NF 35, 2017. <85> Bacterial Endotoxins Test	PASS All samples met the pre-determined acceptance criteria

The biocompatibility and hemocompatibility testing summarized in the table above yielded acceptable (passing) results for all tests conducted. This information demonstrating acceptable biocompatibility and hemocompatibility properties support the claim of substantial equivalence to the predicate device.

Conclusion:

Based on the indications for use, technological characteristics, and performance testing, the SelectFlex 072 Neurovascular Access System has been shown to be appropriate for its intended use and is considered to be substantially equivalent to the SelectFlex 072 Neurovascular Access System, K181000.