July 15, 2019

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

Re: K190749
Device Name: 087 Balloon Guide Catheter System
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous Catheter
Regulatory Class: Class II
Product Code: DQY, MJN
Dated: June 12, 2019
Received: June 14, 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,

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)*

K190749

Device Name
087 Balloon Guide Catheter System

Indications for Use *(Describe)*

The 087 Balloon Guide Catheter System is indicated for use in facilitating the insertion and guidance of an intravascular catheter into a selected blood vessel in the peripheral and neuro vasculature. The balloon provides temporary vascular occlusion during such procedures.

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
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: 310-395-3950
Contact Person: Michele Lucey
Telephone: 603-748-1374

Date Prepared: July 15, 2019

Device Trade Name: 087 Balloon Guide Catheter System

Classification: Class II

Classification Name: Percutaneous Catheter

Product Code(s): DQY, MJN

Regulation Number(s): 870.1250

Predicate Devices: Concentric Medical, FlowGate^{2}™ (K153729)

Indication for Use:

The 087 Balloon Guide Catheter System is indicated for use in facilitating the insertion and guidance of an intravascular catheter into a selected blood vessel in the peripheral and neuro vasculature. The balloon provides temporary vascular occlusion during such procedures.

Device Description

The 087 Balloon Guide Catheter System is a sterile, single-use intravascular catheter. The system consists of:

- 087 Balloon Guide Catheter
- 1cc Inflation Syringe
- 8Fr Peel Away Introducer
- Hub Extension
- Three Way Stopcock

The 087 Balloon Guide Catheter is offered in three effective lengths, 90, 95, and 100 cm. The 087 Balloon Guide Catheter is an 8 French variable stiffness catheter utilizing a bifurcated dual port luer hub on the proximal end and dual radiopaque distal marker bands on each side of the balloon. The catheter shaft is stainless steel coil reinforced. The hub central port is positioned

coaxial to the central lumen to facilitate introduction of interventional devices through the central lumen. The inflation port is positioned at an angle to the central port and is used with the accessory Inflation Syringe to facilitate inflating and deflating the balloon. The 087 Neurovascular Balloon Guide Catheter uses a distal hydrophilic coating to reduce friction between the catheter shaft and the vessel wall.

Performance Testing Summary:

The 087 Balloon Guide Catheter System has successfully completed the following relevant performance testing demonstrating that the device is suitable for its intended use.

Performance Test Summary			
Study Name	Description	Reference Standard	Results
Conditioning, Distribution, and Shelf Life Aging Verification	To demonstrate that the product meets the packaging strength and packaging integrity following accelerated aging to a 6-month shelf life equivalent	ASTM F88 Seal Strength of Flexible Barrier materials ASTM F2096 Standard Test Method for Detecting Gross Leaks in Medical Packaging	Pass All samples met the pre-determined acceptance criteria
Packaging Visual Inspection	To demonstrate that the product meets the packaging visual inspection requirements given	N/A	Pass All samples met the pre-determined acceptance criteria
Visual Surface Requirements	To demonstrate the product satisfies the visual surface requirements	ISO 10555-1:2013 Intravascular catheters - Sterile and single-use catheters - Part 1: General requirements	Pass All samples met the pre-determined acceptance criteria
Dimensional Inspection	To demonstrate that the product meets the dimensional specifications	ISO 10555-1:2013 Intravascular catheters - Sterile and single-use catheters - Part 1: General requirements	Pass All samples met the pre-determined acceptance criteria
Inflation Volume vs Balloon Diameter	To demonstrate that the product meets the inflation volume vs balloon diameter specifications	In consideration of ISO 10555-4:2013 Intravascular Catheters - Sterile and Single-Use Catheters - Part 4: Balloon Dilatation Catheters	Pass All samples met the pre-determined acceptance criteria
Balloon Burst Volume,	To demonstrate that the Balloon is capable of withstanding an injection volume of 1.0 CC.	In consideration of ISO 10555-4:2013 Intravascular Catheters - Sterile and Single-Use Catheters - Part 4: Balloon Dilatation Catheters	Pass All samples met the pre-determined acceptance criteria
Tip Deflection, FG 00100	To demonstrate that the stiffness of the distal end of the product is similar to other marketed devices.	N/A	Pass All samples met the pre-determined acceptance criteria

Performance Test Summary			
Study Name	Description	Reference Standard	Results
Torque Testing	To demonstrate that the product is capable of 720 degrees of rotation about the central lumen axis without failure.	N/A	Pass All samples met the pre-determined acceptance criteria
Peak Tensile	To demonstrate the product satisfies the peak tensile requirements	ISO 10555-1:2013 Intravascular catheters - Sterile and single-use catheters - Part 1: General requirements	Pass All samples met the pre-determined acceptance criteria
Flow Rate	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 pre-determined acceptance criteria
Small Bore Connector Compliance with Standard	To demonstrate that the product meets the requirements	ISO 80369-7 2016, Small-bore connectors for liquids and gases in healthcare applications — Part 7, Connectors for intravascular or hypodermic applications.	Pass All samples met the pre-determined acceptance criteria
Corrosion Resistance	To demonstrate the product satisfies the corrosion resistance requirements	ISO 10555-1:2013 Intravascular catheters - Sterile and single-use catheters - Part 1: General requirements	Pass All samples met the pre-determined acceptance criteria
Radiopacity	To determine the radiopaque characteristics of the device.	ISO 10555-1:2013 Intravascular catheters - Sterile and single-use catheters - Part 1: General requirements ASTM F640-12 Standard Test Methods for Determining Radiopacity for Medical Use	Pass All samples met the pre-determined acceptance criteria
Hub Extension Liquid Leakage Under Pressure	To demonstrate that the product meets the liquid leakage requirements	ISO 10555-1:2013 Intravascular catheters - Sterile and single-use catheters - Part 1: General requirements	Pass All samples met the pre-determined acceptance criteria
Hub Extension Hub Aspiration Air Leakage	To demonstrate that the product meets the liquid leakage requirements	ISO 10555-1:2013 Intravascular catheters - Sterile and single-use catheters - Part 1: General requirements	Pass All samples met the pre-determined acceptance criteria

Performance Test Summary			
Study Name	Description	Reference Standard	Results
Particulates, Coating Integrity	This study was conducted to determine the quantity and size of particles generated during simulated use	AAMI TIR42:10 Evaluation of particulates associated with vascular medical devices USP <788> Particulate Matter in Injections FDA CTQ: Hydrophilic Coated and Hydrophobic Coated Vascular and Neurological Devices, August 2015	Pass All samples met the pre-determined acceptance criteria
Liquid Leakage Under Pressure	To demonstrate that the product meets the liquid leakage requirements given in ISO 10555-1.	ISO 10555-1:2013 Intravascular catheters - Sterile and single-use catheters - Part 1: General requirements	Pass All samples met the pre-determined acceptance criteria
Hub Aspiration Air Leakage	To demonstrate that the product meets the hub aspiration air leakage requirements given in ISO 10555-1.	ISO 10555-1:2013 Intravascular catheters - Sterile and single-use catheters - Part 1: General requirements	Pass All samples met the pre-determined acceptance criteria
Balloon Inflation Fatigue	To demonstrate that there is no degradation of the Balloon after 20 inflation cycles.	In consideration of ISO 10555-4:2013 Intravascular Catheters - Sterile and Single-Use Catheters - Part 4: Balloon Dilatation Catheters	Pass All samples met the pre-determined acceptance criteria
Simulated Use	Evaluation of device performance under simulated use conditions compared to the predicate device	In consideration of ISO 10555-4:2013 Intravascular Catheters - Sterile and Single-Use Catheters - Part 4: Balloon Dilatation Catheters	Pass All samples met the pre-determined acceptance criteria
Flex Fatigue	To demonstrate that the product does not loose structural integrity when used in the tortuous path model.	ISO 10555-1:2013 Intravascular catheters - Sterile and single-use catheters - Part 1: General requirements	Pass All samples met the pre-determined acceptance criteria
Simulated Use Evaluation of the Q'Apel Balloon Guide Catheter	Simulated use under invitro conditions in a cerebral vascular model	N/A	Pass All samples met the pre-determined acceptance criteria

No animal or clinical studies were required to demonstrate substantial equivalence.

Biocompatibility Testing Summary

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

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

Predicate Device Comparison

The following table provides a comparison of the key characteristics of the 087 Balloon Guide Catheter System to the predicate device.

Comparison Chart			
Feature	**Subject Device** 087 Balloon Guide Catheter System	**Predicate device** the 8F FlowGate^{2}™ Balloon Guide Catheter	**Comparison**
Regulatory Clearance/ Approval Reference	K190749	K153729	NA
FDA Classification	Class II	Class II	Same
Product Code(s)	DQY	DQY	Same
Regulation Number	870.1250	870.1250	Same
Regulation Name	Percutaneous Catheter	Percutaneous Catheter	Same
Anatomical Locations	Peripheral and neuro vasculature	Peripheral and neuro vasculature	Same
Material	Commonly used medical grade plastics and stainless steel,	Commonly used medical grade plastics and stainless steel	Similar, difference does not raise new questions regarding safety and efficacy, confirmed through biocompatibility and performance testing
Reinforced Catheter Shaft Reinforcement	Stainless steel coil reinforced	Stainless steel braid reinforced	Similar, minor difference does not raise new questions regarding safety and efficacy, both devices have reinforced catheter walls
Injection Port	Yes	Yes	Same
Radiopacity	Yes, shaft is visible due to coil reinforcement, distal tip Pt-Ir marker bands	Yes, shaft material contains barium sulfate, distal tip Pt-Ir marker band	Similar, minor difference does not raise new questions regarding safety and efficacy, both devices are radiopaque
Marker Band Locations	0.06-in (1.5mm) from the distal tip edge (distal of the balloon) 0.66-in (16.8mm) from the distal tip edge (proximal of the balloon)	.08-in (2mm) from the distal tip edge	Similar, minor difference does not raise new questions regarding safety and efficacy, both devices utilize radiopaque marker bands
Compliant Balloon	Yes, low durometer urethane	Yes, silicone	Similar, material differences do not

Comparison Chart			
Feature	**Subject Device** 087 Balloon Guide Catheter System	**Predicate device** the 8F FlowGate²™ Balloon Guide Catheter	**Comparison**
			raise new questions of safety and efficacy, both materials are used for compliant balloons for intravascular use
Labeled Shaft Outer Diameter	0.110-in (max) (2.79mm) 8Fr	0.106 in (2.7mm) 8Fr	Similar, minor differences do not raise new questions of safety and efficacy
Labelled Shaft Inner Dimension	.087-in (2.21mm) 6.6Fr	0.084-in (2.11mm) 6.4Fr	Similar, minor differences do not raise new questions of safety and efficacy
Effective length	90, 95, 100 cm (35.4, 37.4, 39.4 in)	90cm, 100cm (35.4, 39.4 in)	Same
Tip Shape	Straight	Straight	Same
Maximum Balloon Volume	0.6ml	0.6ml	Same
Injection Port	Yes	Yes	Same
Radiopaque	Distal Tip has radiopaque marker bands, stainless steel reinforcement in the catheter shaft renders the shaft visible on fluoroscopy	Distal Tip has a radiopaque marker band, stainless steel reinforcement in the catheter shaft renders the shaft visible on fluoroscopy	Same
Coating	Hydrophilic Coating – Proximal to the balloon, on the distal Portion	None	Difference does not raise new questions of safety and efficacy. Hydrophillic coatings are commonly used to lubricate vascular catheters. Both devices do not have coating on the balloon region
Internal Construction	Multi Lumen catheter wall	Coaxial lumen	Differences do not raise new questions of safety and

Comparison Chart			
Feature	**Subject Device** 087 Balloon Guide Catheter System	**Predicate device** the 8F FlowGate²™ Balloon Guide Catheter	**Comparison**
			efficacy. Both designs are intended to create a pathway to the side arm for balloon inflation
Reinforced Shaft	Stainless steel reinforced shaft	Stainless steel reinforced shaft	Same
Accessories Supplied	3-Way Stopcock, Peel Away Sheath, Hub extension, 1ml Syringe	Dilator, Rotating Hemostasis Valve, Tuohy Borst Valve with sideport, Peel Away Sheaths, Luer-Activated Valves	Similar, minor differences do not raise new questions of safety and efficacy.
How Supplied	Sterile, single use	Sterile, single use	Same
Sterilization Method	EtO	EtO	Same
Sterility Assurance Level	10^{-6}	10^{-6}	Same

Conclusion:

Q'Apel Medical LLC concludes through a review of the benchtop assessments, the comparison of the device classification, indications for use, operating principle, technological characteristics, sterility, and biocompatibility that the 087 Balloon Guide Catheter System is substantially equivalent to the predicate device, the FlowGate²™ Balloon Guide Catheter. Any differences are minor and do not raise different questions of safety and effectiveness.