DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

January 27,2016

Concentric Medical, Inc.
Mr. Shazia Hakim
Senior Regulatory Affairs Specialist
301 East Evelyn Avenue
Mountain View, California 94041

Re: K153729
Trade/Device Name: 8F FlowGate Balloon Guide Catheter
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous Catheter
Regulatory Class: Class II
Product Code: DQY
Dated: December 22, 2015
Received: December 28, 2015

Dear Mr. Hakim:

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

William J. Heetderks -S

for Carlos L. Peña, PhD, MS
Director
Division of Neurological
and Physical Medicine Devices
Office of Device Evaluation
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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K153729

Device Name
8F FlowGate Balloon Guide Catheter

Indications for Use *(Describe)*

FlowGate Balloon Guide Catheters are indicated for use in facilitating the insertion and guidance of an intravascular catheter into a selected blood vessel in the peripheral and neuro vascular systems. The balloon provides temporary vascular occlusion during these and other angiographic procedures. The Balloon Guide Catheter is also indicated for use as a conduit for Retrieval devices.

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

Device Trade Name: 8F FlowGate^{2}™ Balloon Guide Catheter
Common Name: Percutaneous Catheter

Classification Name: Percutaneous Catheter, 21CFR 870.1250 Class II

Product Code: DQY

Submitter: Concentric Medical, Inc.
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Facility Registration #2954917

Contact: Shazia Hakim
Senior Regulatory Affairs Specialist

Date Prepared: December 22, 2015

Predicate Device:

Primary Predicate Device	
K131492 (clearance granted October 3, 2013)	Modified FlowGate™ Balloon Guide Catheter
Reference Predicate Device	
K122581 (clearance granted November 21, 2012)	Concentric Balloon Guide Catheter

Device Description

Like the predicate device, the 8F FlowGate^{2}™ Balloon Guide Catheter is a coaxial- lumen, braid-reinforced, variable stiffness catheter designed for use in facilitating the insertion and guidance of an intravascular catheter into a selected blood vessel in the peripheral and neuro vascular systems. A radiopaque marker is included on the distal end for angiographic visualization. A compliant balloon is mounted on the distal end to provide temporary vascular occlusion during angiographic procedures. A bifurcated luer hub on the proximal end allows attachments for flushing, inflation and aspiration. Modified FlowGate™ Balloon Guide Catheter dimensions and maximum recommended balloon inflation volume are indicated on product label.

Accessories

The 8F FlowGate^{2}™ Balloon Guide Catheter is packaged with a Dilator, Rotating Hemostasis Valve, Tuohy Borst Valve with Sideport, Peel Away Sheaths, Luer-Activated Valve, and Extension tubing.

Indications for Use

The Indications for Use are the same as the predicate devices and are as follows:

> FlowGate™ Balloon Guide Catheters are indicated for use in facilitating the insertion and guidance of an intravascular catheter into a selected blood vessel in the peripheral and neuro vascular systems. The balloon provides temporary vascular occlusion during these and other angiographic procedures. The Balloon Guide Catheter is also indicated for use as a conduit for Retrieval devices.

Technological Characteristics and Product Feature Comparison

The subject device, 8F FlowGate^{2}™ Balloon Guide Catheter is substantially equivalent to the predicate devices in terms of:

- indications for use
- fundamental scientific technology
- fundamental design
- materials and processes for packaging and sterilization of devices

A tabular comparison of the specific technological characteristics between the predicate devices and subject device is provided below.

Product Feature Comparison of Subject Device with Predicate Devices (K122581, K131492)

Feature	Reference Predicate Device (K122581)	Primary Predicate Device (K131492)	Subject Device	Rationale for difference (if applicable)
Indications for Use	The Concentric Balloon Guide Catheter is indicated for use in facilitating the insertion and guidance of an intravascular catheter into a selected blood vessel in the peripheral and neuro vascular systems. The balloon provides temporary vascular occlusion during these and other angiographic procedures. The Balloon Guide Catheter is also indicated for use as a conduit for Retrieval devices.	Same except for product name as "FlowGate Balloon Guide Catheter"	Same as predicate device (K131492)	Not applicable

Feature	Reference Predicate Device (K122581)	Primary Predicate Device (K131492)	Subject Device	Rationale for difference (if applicable)
Device Description	The Concentric Balloon Guide Catheters are coaxial-lumen, braid-reinforced, variable stiffness catheters designed for use in facilitating the insertion and guidance of an intravascular catheter into a selected blood vessel in the peripheral and neuro vascular systems. A radiopaque marker is included on the distal end for angiographic visualization. A compliant balloon is mounted on the distal end to provide temporary vascular occlusion during angiographic procedures. A bifurcated luer hub on the proximal end allows attachments for flushing, inflation and aspiration. Balloon Guide Catheter dimensions and maximum recommended balloon inflation volume are indicated on product label.	Same except for product name as "FlowGate Balloon Guide Catheter"	Same as predicate device (K131492)	Not applicable
Target Population	Patients undergoing percutaneous interventional procedures	Same	Same	Not applicable
Anatomical Sites	Peripheral and neuro vasculature	Same	Same	Not applicable
Regulatory Status				
Regulation Number	21CFR 870.1250	Same	Same	Not applicable
Regulation Name	Percutaneous Catheter	Same	Same	Not applicable

Feature	Reference Predicate Device (K122581)	Primary Predicate Device (K131492)	Subject Device	Rationale for difference (if applicable)
Regulatory Class	II	Same	Same	Not applicable
Product Code	DQY	Same	Same	Not applicable
Materials				
Outer Jacket- Proximal Shaft	Purple Pebax® 7233 Barium sulfate	Same	Same	Not applicable
Outer Jacket- Distal Shaft	Blue Pebax 6333 Barium sulfate	Same	Same	Not applicable
Inner Jacket- Proximal Shaft	White Polyamide Blend Barium sulfate	Same	Same	Not applicable
Inner Jacket – Proximal Transition	Natural Pebax 7233 Barium sulfate	Same	Same	Not applicable
Inner Jacket – Proximal Mid Shaft	Natural Pebax 5533, Barium sulfate	Same	Same	Not applicable
Inner Jacket – Distal Mid Shaft	Natural Pebax 4033	Same	Same	Not applicable
Inner Jacket – Distal Shaft	White Pebax 2533, Barium sulfate	Same	Same	Not applicable
Distal Tip	White Pebax 2533, Barium sulfate	White Pebax 3533 White Pebax 2533 Barium sulfate	Same as predicate device (K131492)	Not applicable
Balloon Material	NuSil MED 4035 silicone elastomer	NuSil MED 4025 silicone elastomer	Same as predicate device (K131492)	Not applicable
Balloon Bond Adhesive	Loctite 4011 Cyanoacrylate Loctite 3974 UV Adhesive	Same	Same	Not applicable

Feature	Reference Predicate Device (K122581)	Primary Predicate Device (K131492)	Subject Device	Rationale for difference (if applicable)
Braid	304V Stainless Steel	Same	Same	Not applicable
Braid distal end securement	Loctite UV Adhesive	Loctite 4014 Cyanoacrylate	Same as predicate device (K131492)	Not applicable
Liner	Etched PTFE	Same	Same	Not applicable
Marker Band	90% Platinum/10% Iridium	Same	Same	Not applicable
Luer Hub Adhesive	Loctite 3321 UV Adhesive	Same	Same	Not applicable
2-Arm Luer Hub	Polyurethane	Same	Same	Not applicable
Strain Relief	White Pebax 4033 White Polyolefin	White Pebax 4033 White Polyolefin	Same as predicate device (K131492)	Not applicable
Nominal Design Attributes				
Labeled Shaft Outer Diameter	8F (2.7mm)	Same	Same	Not applicable
Labeled Shaft Inner Diameter	6.4F (0.084 inch /2.1 mm)	Same	Same	Not applicable
Maximum outer diameter along effective length	0.108 inch	Same	Same	Not applicable
Effective Lengths	100 cm and 90 cm	95 cm and 85 cm	Same as predicate device (K131492)	Not applicable
Radiopaque Marker Location from Distal Tip	2 mm	0.75 mm	Same as predicate device (K131492)	Not applicable
Radiopaque Marker Length	0.020 inch	Same	Same	Not applicable
Accessories				

Feature	Reference Predicate Device (K122581)	Primary Predicate Device (K131492)	Subject Device	Rationale for difference (if applicable)
Accessory Devices Provided	Dilator (1) Rotating Hemostasis Valve (1) Tuohy Borst Valve with sideport (1) Peel Away Sheaths (2) Luer-Activated Valve (1)	Same as predicate device, with addition of Extension Tubing (1)	Same as predicate device, K131492 except for modified Dilator tip shape and Tuohy Borst Valve with Sideport with smaller ID	The 6F Dilator and Tuohy Borst Valve with Sideport have been modified to meet user preferences. Bench testing has demonstrated that the compatibility of modified 6F Dilator and Tuohy Borst Valve with Sideport with the subject device does not affect the safety and effectiveness of the device.
Tuohy Borst Valve with Sideiport material	ABS body polypropylene cap PVC tubing polycarbonate luer silicone seal LDPE washer/ring	Same	Same as predicate device, K131492 except for Polycarbonate body polycarbonate cap PVC tubing polycarbonate luer silicone seal PTFE washer/ring	The Tuohy Borst Valve with Sideport has been modified to meet user preferences. Bench testing has demonstrated that the compatibility of modified Tuohy Borst Valve with Sideport with the subject device does not affect the safety and effectiveness of the device.

Feature	Reference Predicate Device (K122581)	Primary Predicate Device (K131492)	Subject Device	Rationale for difference (if applicable)
Dilator Shaft material	Blue Pebax Barium sulfate Bismuth subcarbonate (at tip only) Stainless Steel braid wire	Same	Same	Not applicable
Dilator Hub material	White Polycarbonate	Same	Same	Not applicable
Dilator Strain Relief Sleeve material	Green Pebax	Same	Same	Not applicable
Dilator adhesive materials	Cyanoacrylate	Same	Same	Not applicable
Dilator Shaft Outer Diameter (nominal)	0.072 inch (distal), 0.078 inch (proximal)	Same	Same	Not applicable
Dilator Inner Diameter (nominal)	0.041 inch (distal), 0.050" (proximal)	Same	Same	Not applicable
Dilator Effective Length (nominal)	123 cm	Same	Same	Not applicable
Dilator Distal Tip Angle	60°	Same	Same	Not applicable

Feature	Reference Predicate Device (K122581)	Primary Predicate Device (K131492)	Subject Device	Rationale for difference (if applicable)
Dilator Distal Tip Length	1.40 inch	Same	0.67 inches	The tip shape of the 6F Dilator has been shortened to meet user preferences. Bench testing has demonstrated that the compatibility of the shorter distal tip length of the 6F Dilator with the subject device does not affect the safety and effectiveness of the device.
Packaging				
Materials and Configuration	Polyethylene tubes for catheter and dilator, HDPE sterile prep card and packaging card, Tyvek and LLDPE/Nylon Film Pouch, Chipboard carton	Same	Same	Not applicable
Sterilization Method	100% EtO	Same	Same	Not applicable
How Supplied	Sterile, Single Use	Same	Same	Not applicable

Risk Assessment

Risk assessment of the modifications has been conducted in accordance with EN ISO 14971:2012. Concentric Medical, Inc. has determined that the modifications to the predicate devices raise no new questions of safety or effectiveness.

Results of verification and validation testing have demonstrated the subject device is substantially equivalent to the predicate devices. Furthermore, the modifications did not result in any new failure modes nor were there any changes to existing failure modes.

Testing Summary

The results of verification and validation testing conducted on the subject device demonstrate that it performs as designed, and is suitable for its intended use. Specifically, the following tests were performed on the subject device:

Test	**Conclusions**
Modifications to catheter shaft	
Catheter Simulated Use (Retriever/ Microcatheter Compatibility)	Met established acceptance criteria.
Catheter Kink Resistance, Variables (Test Kink Resistance)	Met established acceptance criteria.
Catheter Tip Flexibility (Catheter/ Vessel Interaction)	Met established acceptance criteria.
Torque Transmission	Met established acceptance criteria.
High Pressure Leak	Met established acceptance criteria.
6F Dilator Accessory	
Dimensional Verification	Met established acceptance criteria.
Dilator Shape Retention	Met established acceptance criteria.
Air Leak Resistance	Met established acceptance criteria.
Liquid Leak Resistance	Met established acceptance criteria.
Tensile Strength	Met established acceptance criteria.
High Pressure Leak	Met established acceptance criteria.
Catheter/ Vessel Interaction (Catheter Tip Flexibility)	Met established acceptance criteria.

Test	**Conclusions**
Kink Resistance	Met established acceptance criteria.
Distal Shaft Trackability	Met established acceptance criteria.
Lumen Compatibility	Met established acceptance criteria.
Tuohy Borst Valve with Sideport Accessory	
Hub Gauging	Met established acceptance criteria.
Liquid leakage	Met established acceptance criteria.
Air Leakage	Met established acceptance criteria.
Separation Force	Met established acceptance criteria.
Unscrewing Torque	Met established acceptance criteria.
Ease of Assembly	Met established acceptance criteria.
Resistance to Overriding	Met established acceptance criteria.
Stress Cracking	Met established acceptance criteria.
Catheter Simulated Use (Tuohy Borst Valve with Sideport seal over devices and wires)	Met established acceptance criteria.

Biocompatibility

Biocompatibility testing was completed for the previously cleared devices under **K122581** and **K131492**. These results apply to the subject device because it uses the same materials and processes as previously cleared predicate devices**.** Biocompatibility testing was conducted on the accessories packaged with the previously cleared devices under K131492, which included the modified Tuohy Borst Valve with Sideport to be packaged with the proposed 8F FlowGate^{2} BGC in compliance with EN ISO 10993-1. The results demonstrate that the subject device with its accessories meet biological safety requirements per EN ISO 10993-1: 2009 for externally communicating medical devices with circulating blood contact for less than 24 hours.

Sterilization and Shelf life

The subject device, including its accessories, are sterilized by 100% EtO and have been adopted into a validated sterilization process in accordance with the principles of ISO 11135:2007, ("*Sterilization of health-care products -- Ethylene oxide -- Requirements for the development, validation and routine control of a sterilization process for medical devices"*) and AAMI TIR 28:2009 ("*Product Adoption and Process Equivalency for Ethylene Oxide Sterilization")* without deviations.

Summary of Substantial Equivalence

The subject device is substantially equivalent to the predicate devices with regard to device design, materials, intended use, and patient population. The conclusions drawn from the risk assessments, verification and validation testing conducted demonstrate that the subject device performs as designed and has an equivalent performance profile as the predicate devices.