510(k) Summary

Trade Name:	Modified Balloon Guide Catheter
Common Name:	Percutaneous Catheter
Classification Name:	Percutaneous Catheter, 21CFR 870.1250 Class II
Product Code:	DQY
Submitter:	Concentric Medical, Inc. 301 E. Evelyn Avenue Mountain View, CA 94041 Tel 650-938-2100 Fax 650-237-5230 Facility Registration #2954917
Contact:	Rhoda Santos Principal Regulatory Affairs Specialist
Date Prepared:	September 27, 2013
Predicate Device:	Concentric Balloon Guide Catheter (K112404) Modified Concentric Balloon Guide Catheter (K122581)

OCT 0 3 2013

Device Description

Like the predicate device, the Modified FlowGate™ 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 Modified FlowGate™ 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 identical to that of the predicate device and are as follows:

> 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.

Technological Characteristics and Product Feature Comparison:

The subject device, Modified FlowGate Balloon Guide Catheters is substantially equivalent to the predicate device in terms of:

- indications for use
- materials
- 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 (K112404 and K122581)

Feature	Results		
	Predicate Device, K112404	**Predicate Device, K122581**	**Subject Device, K131492**
Indications for Use	The 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 with reference to marketed name as FlowGate™ Balloon Guide Catheter	Same as predicate device, K122581
Device Description	The Concentric Balloon Guide Catheter is a coaxial-lumen, braided shaft, variable stiffness catheter with a radiopaque marker on the distal end and a bifurcated luer hub on the proximal end. A compliant balloon is mounted on the distal end. BGC dimensions and maximum recommended balloon inflation volume are indicated on product label. If indicated on the product label, a dilator is provided for transition to the guidewire.	Same with reference to marketed name as FlowGate™ Balloon Guide Catheter	Same as predicate device, K122581
Outer /Inner Jacket	Pebax	Same with revisions to transition lengths and material durometers	Same material durometers as K122581, with revisions to transition lengths

Product Feature Comparison of Subject Device with Predicate Devices (K112404 and K122581)

Feature	Results		
	Predicate Device, K112404	**Predicate Device, K122581**	**Subject Device, K131492**
Distal Tip	Pebax	Same with different durometer material than predicate device, K112404	Same with different durometer material than predicate devices
Balloon Material	Silicone	Same with different material durometer than predicate device, K112404	Same with same material durometer as predicate device, K112404
Braid	Stainless Steel	Same	Same
Braid distal end securement	PET heat shrink	Acrylic (Acrylated Urethane)	Cyanoacrylate, with different viscosity than Cyanoacrylate used on predicate devices
Marker Band	Platinum/Iridium	Same	Same
Catheter Hub	Polyurethane	Same	Same
Strain Relief	Polyolefin	Same	Additional Pebax strain relief included with subject device
Labeled Shaft Inner / Outer Diameter (nominal)	Inner Diameter: 0.059" (7F), 0.078" (8F) or 0.085" (9F) Outer Diameter: 0.088 "(7F), 0.104 "(8F) or 0.116" (9F)	Inner Diameter: 0.084in Outer Diameter: 0.106in	Same as predicate device, K122581
Maximum outer diameter along effective length	0.0945"(7F), 0.1080"(8F) or 0.1205" (9F)	0.1080in	Same as predicate device, K122581
Effective Lengths	80cm or 95cm	90cm or 100cm	85cm and 95cm
Distal Tip length	1.5mm	2mm	0.75mm
Radiopaque Marker Length (nominal)	0.0400in	0.0200in	Same as predicate device, K122581

Product Feature Comparison of Subject Device with Predicate Devices (K112404 and K122581)

Feature	Results		
	Predicate Device, K112404	**Predicate Device, K122581**	**Subject Device, K131492**
Accessory Devices Provided	Dilator	Dilator Peel Away Sheath Rotating Hemostatic Valve Tuohy Borst Valve with Sideport Luer Activated Valve	Same as predicate device, K122581 with addition of Extension Tubing
Packaging Materials and Configuration	Polyethylene Tube and HDPE Packaging Card Tyvek/PE/PET Pouch	Polyethylene Tube and HDPE Packaging Card Tyvek/LLDPE Pouch	Same as predicate device, K122581
Sterilization Method	EtO	Same	Same
How Supplied	Sterile, Single Use	Same	Same

Risk Assessment

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

Results of verification and validation testing have demonstrated the Modified FlowGate Balloon Guide Catheters are 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 conducted on the subject device demonstrate that it performs as designed, is suitable for its intended use and is substantially equivalent to the predicate devices. Specifically, the following tests were performed and successfully evaluated on the subject device and accessories:

Dimensional Verification: the ability of the device to meet predetermined dimensional requirements

Simulated Use Testing: the ability of the device and accessories to be used per procedural instructions outlined in the Instructions for Use in a neurovascular model

Balloon Testing: the symmetry and compliance of the distal balloon; balloon inflation and deflation rates; balloon fatigue strength; constrained balloon burst and leakage

Tensile Testing: the mechanical integrity of the device under tensile loads

Distal Shaft Flexibility Testing: the force to flex the distal shaft of the device

Soft Tip Deflection Testing: the force to deflect the distal edge of the soft tip

Tip Patency Testing: the ability of the device distal tip to maintain patency under aspiration

Kink Resistance: the ability of the device shaft to resist kinking

Hub Luer Fitting Testing: compatibility of the Extension Tubing accessory with the hub luer fitting

Extension Tubing Aspiration: the ability to aspirate using the Extension Tubing Accessory

Packaging Verification: the ability of the packaging to protect the finished device following climatic conditioning and distribution simulation

Shelf life testing (Product and Packaging)

The subject device uses the same materials and processes as the predicate devices (K112404 and K122581). Biocompatibility tests were performed on the predicate devices (K112404 and K122581); results for all tests met the acceptance criteria and apply to the subject device. In addition, some biocompatibility screening tests were also performed on the subject device. The biocompatibility tests conducted on the predicate device K122581 and the subject device are summarized in the tables below:

Biocompatibility Tests, Results, Conclusions (Predicate device, K122581)

ISO 10993 Standard	Test	Results	Conclusion
ISO 10993-10	Sensitization Kligman Maximization Test – ISO	The USP 0.9% Sodium Chloride for Injection (NaCl) and Cottonseed Oil (CSO) extracts of the test article showed no evidence of causing delayed dermal contact sensitization.	Non-sensitizer
ISO 10993-5	Cytotoxicity L929 MEM Elution Test	No biological activity (Grade 0) was observed in the L929 mammalian cells at 48 hours post exposure to the test article extract. The observed cellular response obtained from the positive control article extract (Grade 4) and negative control article extract (Grade 0) confirmed the suitability of the test system.	Non-cytotoxic
ISO 10993-10	Intracutaneous Reactivity Intracutaneous Injection Test	The sites injected with the USP 0.9% Sodium Chloride for Injection (NaCl) and Cottonseed Oil (CSO) extracts of the test article did not show a significantly greater biological reaction than the sites injected with the control extracts. The difference of the overall mean score between the test article and the control article was 0.0.	Non-irritant
ISO 10993-11	Systemic Toxicity (Acute) Systemic Injection Test	The 0.9% Sodium Chloride for Injection (NaCl) and Cottonseed Oil (CSO) extracts of the test article did not induce a significantly greater biological reaction than the control extracts, when tested in Swiss Albino mice.	No acute systemic toxicity

Biocompatibility Tests, Results, Conclusions (Predicate device, K122581), continued

ISO 10993 Standard	Test	Results	Conclusion
ISO 10993-11 USP 34 <151>	Systemic Toxicity Rabbit Pyrogen Test, Material Mediated	No rabbit injected with the USP 0.9% Sodium Chloride for Injection (NaCl) extract of the test article showed an individual rise in temperature of 0.5°C or more above the baseline temperature.	Non-pyrogenic
ASTM F756	Hemocompatibility Hemolysis – Rabbit Blood – ASTM Direct and Indirect Contact	The test article exhibited 0.17% hemolysis above the level of hemolysis exhibited by the negative control via the direct method and 0.12% hemolysis above the level of hemolysis exhibited by the negative control via the indirect method.	Non-hemolytic
ISO 10993-4	Hemocompatibility Complement Activation Assay	The plasma exposed to test article exhibited no statistically significant increase in C3a when compared to the untreated control and the negative control after 90 minute exposure. The plasma exposed to test article exhibited a statistically significant increase in SC5b-9 when compared to the untreated control and the negative control after 90 minute exposure.	Minimal complement activation potential
ISO 10993-4	Hemocompatibility Thrombogenicity Study in Dogs	No significant thrombosis with a Grade of 0 (a very small clot is acceptable) was observed in 1 out of 2 test sites and 1 out of 2 control sites. Minimal thrombosis with a Grade of 1 (thrombus found at one location) was observed in 1 out of 2 test sites and 1 out of 2 control sites.	No significant thrombosis

Biocompatibility Screening Tests, Results, Conclusions (Subject device, K131492)

ISO 10993 Standard	Test	Results	Conclusion
ISO 10993-5	Cytotoxicity L929 MEM Elution Test	No cyctotoxicity or cell lysis was noted in any of the test wells. No pH shift was observed at 48 hours. The reagent control, negative control and the positive control performed as anticipated.	Non-cytotoxic
ISO 10993-4	Hemocompatibility ASTM Hemolysis (Direct contact and extract test)	The hemolytic index for the test article in direct contact with blood was 0.0% and the hemolytic index for the test article extract was 0.4%	Non-hemolytic
ISO 10993-18	Fourier Transform Infrared (FTIR) Scan (+ control sample)	The distal 1mm white tip was scanned and compared to the control sample. The samples had a match of 97.90%.	Materials for test article and control sample are equivalent.
ISO 10993-18	Physicochemical Tests Plastics (USP <661>)	Non-volatile residue: 1 mg Residue on ignition: < 1 mg Heavy metal: < 1 ppm Buffering capacity: < 1.0 ml	Met USP <661> requirements

The biocompatibility results demonstrate that the subject device is biocompatible.

Summary of Substantial Equivalence

The subject device, Modified FlowGate Balloon Guide Catheter, 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, is as safe, as effective, and performs as well as or better than the predicate devices.

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

October 3, 2013

Concentric Medical, Inc.
% Ms. Rhoda Santos
Principal Regulatory Affairs Specialist
301 East Evelyn Avenue
Mountain View, CA 94041

Re: K131492
Trade/Device Name: Modified FlowGate™ Balloon Guide Catheter
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous Catheter
Regulatory Class: Class II
Product Code: DQY
Dated: August 21, 2013
Received: August 22, 2013

Dear Ms. Santos:

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 Small Manufacturers, International and Consumer Assistance 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" (21CFR 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 Small Manufacturers, International and Consumer Assistance 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,

Joyce M. Whang -S

for Victor Krauthamer, Ph.D.
Acting Division Director
Division of Neurological and Physical
Medicine Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K131492

Device Name: Modified FlowGate™ Balloon Guide Catheter

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.

Prescription Use ✓ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of Center for Devices and Radiological Health (CDRH)

Joyce M. Whang -S