May 9, 2025

Crossroads Neurovascular, Inc.
℅ Ryan Breckenridge
QA/RA Consultant
M4D LLC
105 North Pointe Drive, Suite D
Lake Forest, California 92630

Re: K242392
Trade/Device Name: PATH BGC
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous Catheter
Regulatory Class: Class II
Product Code: QJP
Dated: March 28, 2025
Received: April 07, 2025

Dear Ryan Breckenridge:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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 -S

Naira Muradyan, Ph.D.
Assistant Director
DHT5A: Division of Neurosurgical,
Neurointerventional, and
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Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K242392

Device Name
PATH BGC

Indications for Use *(Describe)*
PATH BGC is indicated for use in facilitating the insertion and guidance of an intravascular catheter into a selected blood vessel in the neurovascular system. The balloon provides temporary vascular occlusion during these and other angiographic 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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(k) Summary – K242392
As required by 21 CFR 807.92

Applicant:	Crossroads Neurovascular, Inc. 105 North Pointe Drive, Suite D Lake Forest, CA 92630
Contact:	Ryan Breckenridge Telephone: 760-917-1294 Email: ryan.breckenridge@m4dllc.com
Date Prepared:	May 07, 2025
Device Trade Name:	PATH BGC
Device Common Name:	Balloon Guide Catheter
Classification Name:	Catheter, Percutaneous
Regulation Number:	21 CFR 870.1250
Product Code:	QJP
Predicate Device:	Modified FlowGate Balloon Guide Catheter, K131492

Device Description

The PATH Balloon Guide Catheter (PATH BGC) is a dual coaxial lumen catheter consisting of an inner coil reinforced variable stiffness lumen and an outer braid reinforced variable stiffness lumen. A radiopaque marker is included at the tip of the catheter and at the distal and proximal ends of the balloon. A compliant balloon is mounted near the distal end of the catheter to provide vascular occlusion during angiographic procedures. The catheter has hydrophilic coating at the distal and proximal end. A bifurcated luer hub on the proximal end allows attachments for flushing and balloon inflation.

Indications For Use

PATH BGC is indicated for use in facilitating the insertion and guidance of an intravascular catheter into a selected blood vessel in the neurovascular system. The balloon provides temporary vascular occlusion during these and other angiographic procedures.

Comparison of Predicate and Subject Devices

The table below provides the comparison of technological characteristics and indications for use of the subject device with the predicate device.

Table 1: Comparison of Predicate and Subject Devices

Feature	**Predicate Device** **Modified FlowGate Balloon Guide Catheter**	**Subject Device** **PATH BGC**
	K131492	K242392
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.	PATH BGC is indicated for use in facilitating the insertion and guidance of an intravascular catheter into a selected blood vessel in the neurovascular system. The balloon provides temporary vascular occlusion during these and other angiographic procedures.
Device Description	The FlowGate 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. Balloon Guide Catheter dimensions and maximum recommended balloon inflation volume are indicated on the product label.	The PATH BGC is a dual coaxial lumen catheter consisting of an inner coil reinforced variable stiffness lumen and an outer braid reinforced variable stiffness lumen. A radiopaque marker is included at the tip of the catheter and at the distal and proximal ends of the balloon. A compliant balloon is mounted near the distal end of the catheter to provide vascular occlusion during angiographic procedures. A bifurcated luer hub on the proximal end allows attachments for flushing and balloon inflation.
Outer Jacket	Pebax	Neusoft UR862A Pebax
Inner Jacket	Pebax	Neusoft UR862A Pebax
Distal Tip	Pebax	Polyurethane

Feature	Predicate Device Modified FlowGate Balloon Guide Catheter	Subject Device PATH BGC
	K131492	K242392
Balloon Material	Silicone	Polyurethane
Braid	Stainless Steel	Stainless Steel
Braid Distal End Securement	Cyanoacrylate	Cyanoacrylate
Marker Band	Platinum/Iridium	Platinum/Iridium
Catheter Hub	Polyurethane	Polycarbonate
Strain Relief	Polyolefin/Pebax	Polyurethane
Labeled Shaft Inner/Outer Diameter (Nominal)	Inner Diameter: 0.084in Outer Diameter: 0.106in	Inner Diameter: 0.070in Outer Diameter: 0.0965in
Maximum Outer Diameter Along Effective Length	0.1080in	0.0965in
Effective Lengths	85cm and 95cm	90cm, 95cm, 100cm, and 105cm
Distal Tip Length	0.75mm	2cm
Radiopaque Marker Length (Nominal)	0.020in	0.035in
Accessory Devices Provided	Dilator Peel Away Sheath Rotating Hemostatic Valve Tuohy Borst Valve with Sideport Luer Activated Valve Extension Tubing	Peel Away Sheath Rotating Hemostatic Valve with Sideport Luer Activated Valve
Packaging Materials & Configuration	Polyethylene Tube and HDPE Packaging Card Tyvek/LLDPE Pouch	Polyethylene Tube and HDPE Packaging Card Tyvek/LLDPE Pouch

Feature	Predicate Device Modified FlowGate Balloon Guide Catheter	Subject Device PATH BGC
	K131492	K242392
Sterilization Method	EtO	EtO
How Supplied	Sterile, Single Use	Sterile, Single Use

To establish substantial equivalence of the subject device and ensure the device meets the design specifications and requirements, non-clinical bench performance and biocompatibility testing were conducted per the risk analysis. The testing performed and results are summarized below.

Design Verification Testing – Bench

Performance testing was conducted to support the PATH BGC submission. The results of the design verification and validation testing (Table 2) confirm that the subject device conforms to the pre-defined specifications and test acceptance criteria are met.

Table 2: PATH BGC Bench Testing Summary

Test	Description	Results
Visual Inspection	To verify the visual surface requirements are met.	Pass – all samples met the pre-determined acceptance criteria.
Dimensional Inspection	To verify the dimensional specifications are met.	Pass – all samples met the pre-determined acceptance criteria.
Simulated Use	To evaluate the performance of the device and accessories in simulated anatomy model.	Pass – all samples met the pre-determined acceptance criteria.
Kink Resistance	To evaluate the device around bends of clinically relevant radii and verify kink resistance requirements are met.	Pass – all samples met the pre-determined acceptance criteria.
Coating Lubricity	To evaluate frictional forces and verify coating lubricity requirements are met.	Pass – all samples met the pre-determined acceptance criteria.
Radiopacity	To evaluate marker band visibility under fluoroscopy.	Pass – all samples met the pre-determined acceptance criteria.
Delivery/Retrieval	To evaluate the device in an anatomical model and determine the maximum forces required to completely deliver and retrieve the PATH BGC.	Pass – all samples met the pre-determined acceptance criteria.
Balloon Deflation Time	To verify balloon deflation time requirements are met.	Pass – all samples met the pre-determined acceptance criteria.
Distal Tip Stiffness	To evaluate distal tip deflection force and verify distal tip stiffness requirements are met.	Pass – all samples met the pre-determined acceptance criteria.
Coating Integrity	To evaluate device pre- and post-insertion and retrieval through a simulated vascular model and verify coating integrity requirements are met.	Pass – all samples met the pre-determined acceptance criteria.

Torque Strength	To evaluate device integrity after applied hub rotations with distal end held stationary and verify torque strength requirements are met.	Pass – all samples met the pre-determined acceptance criteria.
Shaft & Hub Tensile	To verify tensile strength requirements are met.	Pass – all samples met the pre-determined acceptance criteria.
Liquid Leak	To verify liquid leak requirements per ISO 10555-1 are met.	Pass – all samples met the pre-determined acceptance criteria.
Air Leak	To verify air leak requirements per ISO 10555-1 are met.	Pass – all samples met the pre-determined acceptance criteria.
Hub Compatibility	To verify BGC bifurcated luer hub requirements per ISO 80369-7 are met.	Pass – all samples met the pre-determined acceptance criteria.
RHV Luer	To verify RHV luer requirements per ISO 80369-7 are met.	Pass – all samples met the pre-determined acceptance criteria.
Static Burst	To verify static burst requirements per ISO 10555-1 are met.	Pass – all samples met the pre-determined acceptance criteria.
Dynamic Burst	To verify dynamic burst requirements per ISO 10555-1 are met.	Pass – all samples met the pre-determined acceptance criteria.
Resistance to Lumen Collapse	To demonstrate that the main lumen does not collapse under aspiration.	Pass – all samples met the pre-determined acceptance criteria.
Corrosion Resistance	To verify corrosion resistance requirements per ISO 10555-1 are met.	Pass – all samples met the pre-determined acceptance criteria.
Particulate	To evaluate the device within a simulated anatomy model and verify particulate count is similar to the comparator device.	Pass – all samples met the pre-determined acceptance criteria.
Balloon Fatigue	To evaluate repetitive balloon inflation and deflation cycles and verify fatigue requirements are met.	Pass – all samples met the pre-determined acceptance criteria.
Balloon Burst Volume	To verify balloon burst volume requirements are met.	Pass – all samples met the pre-determined acceptance criteria.
Balloon Diameter to Inflation Volume (Compliance)	To characterize balloon diameter for pre-defined balloon inflation volumes.	All samples were characterized.
Shelf Life	To verify device performance after accelerated aging.	Pass – all samples met the pre-determined acceptance criteria.
Transit Testing	To subject the device, accessories, and packaging to environmental conditioning and shipping simulation and verify performance requirements are met.	Pass – all samples met the pre-determined acceptance criteria.
Packaging – Bubble Leak	To evaluate packaging per ASTM F2096-11 and verify requirements are met.	Pass – all samples met the pre-determined acceptance criteria.
Packaging – Pouch Seal Strength	To evaluate packaging per ASTM F88 Technique A (unsupported peel) and verify requirements are met.	Pass – all samples met the pre-determined acceptance criteria.

Sterility	To subject the device, accessories, and packaging to sterilization and verify the requirements are met.	Pass – all samples met the pre-determined acceptance criteria.

Animal Study
Animal study was not deemed necessary to demonstrate substantial equivalence.

Sterilization and Shelf Life
The subject device is sterilized using an Ethylene Oxide (EtO) sterilization cycle. The sterilization cycle was verified to ensure a sterility assurance level (SAL) of 10^{-6} in accordance with ISO 11135:2014, "Sterilization of health-care products – Ethylene oxide – Requirements for the development, validation, and routine control of a sterilization process for medical devices."

Shelf-life studies for the subject device have demonstrated that the subject device and packaging remain functional for the labeled use by date. Shelf-life studies for packaging integrity, seal strength, and device functionality were performed and met all acceptance criteria.

Biocompatibility
Biocompatibility evaluation for the subject device was performed in accordance with ISO 10993-1:2018, "Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process," and Good Laboratory Practice (GLP). Biocompatibility testing completed on the PATH Balloon Guide Catheter and tissue-contacting accessories (Luer Activated Valve, Peel-Away Sheath, and RHV) is summarized in Table 3.

Table 3: Biocompatibility Testing

Test	Standard	Results	Conclusion
Minimum Essential Medium (1X MEM) Cytotoxicity (GLP)	ISO 10993-5	Test article scored 0 at 48 hours. 1X MEM test extract showed no cytotoxic potential to L-929 mouse fibroblast cells undiluted or at any dilution.	Non-cytotoxic
Intracutaneous Irritation (GLP – 2 Extracts)	ISO 10993-23	The delta between the average scores of the extract of the test article and the vehicle control are 0.0; 0.2.	Non-irritant
Guinea Pig Maximization Sensitization (GLP – 2 Extracts)	ISO 10993-10	Test and control animal's response not greater than "0".	Non- sensitizing
Acute Systemic Toxicity (GLP – 2 Extracts)	ISO 10993-11	None of the animals were observed with abnormal clinical signs indicative of toxicity for 72 hours. All were alive at the end of 72 hours and body weight changes were within acceptable parameters.	Non-toxic
Material-Mediated Rabbit Pyrogen (GLP)	ISO 10993-11, USP <151>	No rabbit temperature rise ≥0.5°C.	Non-pyrogenic
Complement Activation Assay with Comparison Article (GLP)	ISO 10993-4, ASTM F756, ASTM 2382, ASTM F2888	Results were within acceptable range and not statistically different than	Not an activator of the complement system

		activated normal human serum (NHS) control or negative control.	
Hemolysis – Direct Contact and Extract Method (GLP)		Direct Contact Blank corrected hemolytic index: -0.3. Extract Blank corrected hemolytic index: -0.4.	Non-hemolytic
A GLP 4-Hour Thrombogenicity Study in Ovine		Test articles were compared to the comparator.	Thromboresistance of the test device is similar to the comparator.
Partial Thromboplastin Time (PTT) (GLP)		Test article was found to be 90.3% of the negative control and not statistically different from the comparator.	
Heparinized Blood Platelet and Leukocyte Count Assay		Test article was found to be 108.0% and 90.4% of the negative control (for platelet and leukocyte cell, respectively) and not statistically different from the comparator.	

Clinical Study

Clinical study was not deemed necessary to demonstrate substantial equivalence.

Conclusion

The PATH BGC and the predicate device, Modified FlowGate Balloon Guide Catheter (K131492), have similar intended use, device operating principle, technological characteristics, and indications for use. The differences in technological characteristics do not raise new questions of safety or effectiveness. Successful completion of non-clinical bench performance testing, biocompatibility, sterility, and shelf-life testing demonstrates that the subject device meets the design specifications and functions as intended. Based on the information provided in this submission, the PATH BGC is substantially equivalent to the predicate, Modified FlowGate Balloon Guide Catheter (K131492).