April 15, 2026

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

Re: K260938
Trade/Device Name: PATH BGC
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous Catheter
Regulatory Class: Class II
Product Code: QJP
Dated: March 20, 2026
Received: March 20, 2026

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 Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (Preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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 Management System Regulation (QMSR) (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,

JAIME RABEN -S

for Naira Muradyan
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: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K260938

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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510(k) Summary – K260938
As required by 21 CFR 807.92

I. SUBMITTER

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:	April 14, 2026

II. DEVICE

Device Trade Name:	PATH BGC
Device Common Name:	Balloon Guide Catheter
Classification Name:	Catheter, Percutaneous
Regulation Number:	21 CFR 870.1250
Product Code:	QJP

III. PREDICATE DEVICE

Predicate Device:	PATH BGC Balloon Guide Catheter, K242392

IV. 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.

V. 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.

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

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** **PATH BGC**	**Subject Device** **PATH BGC**
	K242392	K260938
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.	Same
Device Description	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. 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.	Same
Outer Jacket	Neusoft UR862A Pebax	Same
Inner Jacket	Neusoft UR862A Pebax	Same
Distal Tip	Polyurethane	Same
Balloon Material	Polyurethane	Same
Braid	Stainless Steel	Same
Braid Distal End Securement	Cyanoacrylate	Same
Marker Band	Platinum/Iridium	Same
Catheter Hub	Polycarbonate	Same
Strain Relief	Polyurethane	Same

Feature	Predicate Device PATH BGC	Subject Device PATH BGC
	K242392	K260938
Labeled Shaft Inner/Outer Diameter (Nominal)	Inner Diameter: 0.070in Outer Diameter: 0.0965in	Same
Maximum Outer Diameter Along Effective Length	0.0965in	Same
Effective Lengths	90cm, 95cm, 100cm, and 105cm	Same
Distal Tip Length	2cm	Same
Radiopaque Marker Length (Nominal)	0.035in	Same
Accessory Devices Provided	Peel Away Sheath Rotating Hemostatic Valve with Sideport Luer Activated Valve	Same
Packaging Materials & Configuration	Polyethylene Tube and HDPE Packaging Card Tyvek/LLDPE Pouch	Same
Sterilization Method	Ethylene oxide (EtO)	Same
How Supplied	Sterile, Single Use	Same

VII. PERFORMANCE DATA

To establish substantial equivalence of the subject device and ensure the device meets the design specifications and requirements, non-clinical bench performance testing was 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.	This characteristic is unchanged and relies on the successful testing from the predicate K242392.
Dimensional Inspection	To verify the dimensional specifications are met.	This characteristic is unchanged and relies on the successful testing from the predicate K242392.
Simulated Use	To evaluate the performance of the device and accessories in simulated anatomy model.	This characteristic is unchanged and relies on the

		successful testing from the predicate K242392.
Kink Resistance	To evaluate the device around bends of clinically relevant radii and verify kink resistance requirements are met.	This characteristic is unchanged and relies on the successful testing from the predicate K242392.
Coating Lubricity	To evaluate frictional forces and verify coating lubricity requirements are met.	This characteristic is unchanged and relies on the successful testing from the predicate K242392.
Radiopacity	To evaluate marker band visibility under fluoroscopy.	This characteristic is unchanged and relies on the successful testing from the predicate K242392.
Delivery/Retrieval	To evaluate the device in an anatomical model and determine the maximum forces required to completely deliver and retrieve the PATH BGC.	This characteristic is unchanged and relies on the successful testing from the predicate K242392.
Balloon Deflation Time	To verify balloon deflation time requirements are met.	This characteristic is unchanged and relies on the successful testing from the predicate K242392.
Distal Tip Stiffness	To evaluate distal tip deflection force and verify distal tip stiffness requirements are met.	This characteristic is unchanged and relies on the successful testing from the predicate K242392.
Coating Integrity	To evaluate device pre- and post-insertion and retrieval through a simulated vascular model and verify coating integrity requirements are met.	This characteristic is unchanged and relies on the successful testing from the predicate K242392.
Torque Strength	To evaluate device integrity after applied hub rotations with distal end held stationary and verify torque strength requirements are met.	This characteristic is unchanged and relies on the successful testing from the predicate K242392.
Shaft & Hub Tensile	To verify tensile strength requirements are met.	This characteristic is unchanged and relies on the successful testing from the predicate K242392.
Liquid Leak	To verify liquid leak requirements per ISO 10555-1 are met.	This characteristic is unchanged and relies on the successful testing from the predicate K242392.
Air Leak	To verify air leak requirements per ISO 10555-1 are met.	This characteristic is unchanged and relies on the successful testing from the predicate K242392.
Hub Compatibility	To verify BGC bifurcated luer hub requirements per ISO 80369-7 are met.	This characteristic is unchanged and relies on the successful testing from the predicate K242392.
RHV Luer	To verify RHV luer requirements per ISO 80369-7 are met.	This characteristic is unchanged and relies on the successful testing from the predicate K242392.

Static Burst	To verify static burst requirements per ISO 10555-1 are met.	This characteristic is unchanged and relies on the successful testing from the predicate K242392.
Dynamic Burst	To verify dynamic burst requirements per ISO 10555-1 are met.	This characteristic is unchanged and relies on the successful testing from the predicate K242392.
Resistance to Lumen Collapse	To demonstrate that the main lumen does not collapse under aspiration.	This characteristic is unchanged and relies on the successful testing from the predicate K242392.
Corrosion Resistance	To verify corrosion resistance requirements per ISO 10555-1 are met.	This characteristic is unchanged and relies on the successful testing from the predicate K242392.
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.	This characteristic is unchanged and relies on the successful testing from the predicate K242392.
Balloon Burst Volume	To verify balloon burst volume requirements are met.	This characteristic is unchanged and relies on the successful testing from the predicate K242392.
Balloon Diameter to Inflation Volume (Compliance)	To characterize balloon diameter for pre-defined balloon inflation volumes.	This characteristic is unchanged and relies on the successful testing from the predicate K242392.
Shelf Life	To verify device performance after accelerated aging.	This characteristic is unchanged and relies on the successful testing from the predicate K242392.
Transit Testing	To subject the device, accessories, and packaging to environmental conditioning and shipping simulation and verify performance requirements are met.	This characteristic is unchanged and relies on the successful testing from the predicate K242392.
Packaging – Bubble Leak	To evaluate packaging per ASTM F2096-11 and verify requirements are met.	This characteristic is unchanged and relies on the successful testing from the predicate K242392.
Packaging – Pouch Seal Strength	To evaluate packaging per ASTM F88 Technique A (unsupported peel) and verify requirements are met.	This characteristic is unchanged and relies on the successful testing from the predicate K242392.
Sterility	To subject the device, accessories, and packaging to sterilization and verify the requirements are met.	This characteristic is unchanged and relies on the successful testing from the predicate K242392.

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

Sterilization and Shelf Life
Sterilization and shelf life testing was not deemed necessary to demonstrate substantial equivalence, since the change has no impact to device sterilization nor shelf life.

Biocompatibility
Biocompatibility testing was not deemed necessary to demonstrate substantial equivalence, since the change has no impact to device biocompatibility.

Clinical Study
A clinical study was not deemed necessary to demonstrate substantial equivalence.

VIII. CONCLUSIONS

The PATH BGC Balloon Guide Catheter and the predicate device, PATH BGC Balloon Guide Catheter, (K242392), 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 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, PATH BGC Balloon Guide Catheter, (K242392).