December 19, 2024

Stryker Neurovascular
Shazia Hakim
Principal Regulatory Affairs Specialist
47900 Bayside Parkway
Fremont, California 94538

Re: K241768
Trade/Device Name: Broadway 8 Catheter
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous Catheter
Regulatory Class: Class II
Product Code: QJP
Dated: November 19, 2024
Received: November 20, 2024

Dear Shazia 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 (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,

Sara S. Thompson -S

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

510(k) Number *(if known)*
K241768

Device Name
Broadway 8 Catheter

Indications for Use *(Describe)*
The Broadway 8 Catheter is indicated for use in facilitating the insertion and guidance of appropriately sized interventional devices into a selected blood vessel in the neurovascular system.

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.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) Summary

Submitter	Stryker Neurovascular 47900 Bayside Parkway Fremont, CA 94538 Phone: 510-413-2500
Contact	Shazia Hakim
Date Prepared	June 19, 2024
Device Name	Broadway 8 Catheter
Common Name	Percutaneous Catheter
Classification Name	Catheter, Percutaneous, Neurovasculature (21 CFR 870.1250)
Product Code	QJP
Device Classification	Class II
Predicate Device	AXS Vecta Intermediate Catheter (AXS Vecta 74), K200206

Device Description

The Broadway 8 Catheter is a single lumen, flexible, variable stiffness catheter designed for use in facilitating the insertion and guidance of appropriately sized interventional devices into a selected blood vessel in the neurovascular system. It has a radiopaque marker band on the distal end and a luer hub at the proximal end. The Broadway 8 Catheter shaft has a lubricious hydrophilic coating at the distal end to reduce friction during use. It is packaged with a FastPass Delivery Assist Catheter, two rotating hemostasis valves (RHVs) and two peel-away introducer sheaths.

The FastPass Delivery Assist Catheter may be used in conjunction with the Broadway 8 Catheter to facilitate the introduction of the Broadway 8 Catheter into distal vasculature and aid in navigation to distal anatomy. The FastPass Delivery Assist Catheter has a lubricious hydrophilic coating at the distal end to reduce friction during use.

Indications for Use

The Broadway 8 Catheter is indicated for use in facilitating the insertion and guidance of appropriately sized interventional devices into a selected blood vessel in the neurovascular system.

Technological Characteristics and Product Feature Comparison

Stryker Neurovascular has demonstrated the Broadway 8 Catheter is substantially equivalent to the Predicate Device, AXS Vecta Intermediate Catheter based on the same or similar materials, similar design, and the same fundamental operating principles. A comparison of the Subject Device with the Predicate Device is summarized in **Table 1** below.

Table 1: Substantial Equivalence Comparison

Detail	**Broadway 8 Catheter** (Subject Device)	**AXS Vecta Intermediate Catheter (AXS Vecta 74)** (Predicate Device)
Regulation Number	21 CFR 870.1250	Same
Classification	II	Same
FDA Product Code	QJP	QJP, DQY
510(k) Number	K241768	K200206
Indications for Use	The Broadway 8 Catheter is indicated for use in facilitating the insertion and guidance of appropriately sized interventional devices into a selected blood vessel in the neurovascular system.	The AXS Vecta Intermediate Catheter is indicated for use in facilitating the insertion and guidance of appropriately sized interventional devices into a selected blood vessel in the peripheral and neurovascular systems. The AXS Vecta Intermediate Catheter is also indicated for use as a conduit for retrieval devices.
Materials	Commonly used medical grade plastics & metals with hydrophilic coating.	Same
Strain Relief	None	Polyolefin
Reinforcement	Stainless Steel	Stainless Steel/Nitinol
Coating	Hydrophilic Coating	Hydrophilic Coating
Outer Diameter	0.098 in.	Distal OD: AXS Vecta 71: 0.082 in. AXS Vecta 74: 0.083 in. Proximal OD: AXS Vecta 71: 0.085 in. AXS Vecta 74: 0.087 in.
Inner Diameter	0.084 in.	AXS Vecta 71: 0.071 in. AXS Vecta 74: 0.074 in.
Effective Length(s)	132 cm	115, 125, 132 cm
Sterilization Method	EO Sterilization	Same
How Supplied	Single Use/Sterile	Same

Detail	**Broadway 8 Catheter** (Subject Device)	**AXS Vecta Intermediate Catheter (AXS Vecta 74)** (Predicate Device)
Accessory Devices Provided	2 Hemostasis Valves, 2 Peel-Away Introducers FastPass Delivery Assist Catheter (ID: 0.016"; Distal OD: 0.033"; Bulb OD: 0.075", Length: 156cm)	Hemostasis Valve, 2 Peel-Away Introducers Scout Introducer

Risk Assessment

Risk assessment of the Broadway 8 Catheter has been conducted in accordance with EN ISO 14971 and Stryker Neurovascular risk management procedures. Stryker Neurovascular has determined that the Broadway 8 Catheter raises no new questions of safety or effectiveness. The risk assessment conducted on the Subject Device did not result in any new hazards or harms, and no significant changes to the occurrences of harm were identified when compared with the Predicate Device.

Testing Summary

Performance Data – Bench

The results of design verification and design validation testing conducted on the Broadway 8 Catheter demonstrate that it performs as designed, is suitable for the indication for use, and is substantially equivalent to the legally marketed Predicate Device. The design verification and design validation bench testing are summarized in **Table 2** below:

Table 2: Performance Data – Bench Testing

Test	Test Method Summary	Conclusions
Dimensional Verification	Verification of critical dimensions.	Pass – Samples met established acceptance criteria.
Tensile Strength	Tensile strength tested per ISO 10555-1.	Pass – Samples met established acceptance criteria.
Torsional Bond Strength	The test specimens were rotated to evaluate integrity after rotation.	Pass – Samples met established acceptance criteria

Test	Test Method Summary	Conclusions
Particulate	Particulate was collected from simulated use in a tortuous model, characterized by size and particulate type, and compared to commercially available product.	Pass – Device comparable to predicate.
Coating Integrity	Hydrophilic coating was inspected before and after simulated use in a tortuous model.	Pass – Device comparable to predicate
Liquid Leak	Liquid leak tested per ISO 10555-1.	Pass – Samples met established acceptance criteria.
Air Leak	Air leak tested per ISO 10555-1.	Pass – Samples met established acceptance criteria.
Kink Resistance	Measurement of catheter kink radius	Pass – Samples met established acceptance criteria
Burst Pressure	Burst Pressure was tested per ISO 10555-1.	Pass – Samples met established acceptance criteria
Liner Lamination	Verification of inner liner adherence following simulated use.	Pass – Samples met established acceptance criteria
Chemical Compatibility	Catheter was measured and visually inspected before and after exposure to various clinically relevant chemicals.	Pass – Samples met established acceptance criteria
Tip Buckling	Measurement of distal catheter buckling force.	Pass – Samples met established acceptance criteria
Product Integrity Post-Removal	Catheter and accessories were inspected following removal from packaging.	Pass – Samples met established acceptance criteria.
Simulated Use Testing	Simulated use testing in a bench anatomical model using worst-case interventional devices with femoral artery access.	Pass – Samples met established acceptance criteria.
Friction Force Testing	Coating lubricity measured by a pinch test and compared to predicate device.	Pass – Device comparable to predicate

Performance Data – Animal Study

An animal study was conducted in compliance with FDA Good Laboratory Practice (GLP) Regulation (21 CFR Part 58) at 3-day and 30-day timepoints to assess the navigation to the target artery (3 passes in each artery), angiography, necropsy, and histopathology of the Subject Device, Broadway 8 Catheter, compared to the Predicate Device, AXS Vecta 74 Catheter. The vessels evaluated in the swine model included the ascending pharyngeal artery (APA), internal maxillary artery (IMAX), internal mammary artery (IMA), superficial cervical artery (SCA), and axillary artery. All study endpoints were met and the Broadway 8 Catheter (Test Article) performed as well as or better than the AXS Vecta 74 catheter (Control Article), with no vessel damage observed at the treatment or terminal procedures. The study results demonstrated vascular safety of the Broadway 8 Catheter. This study supports substantial equivalence of the Broadway 8 Catheter to the Predicate Device as evidenced by the absence of vascular damage at the treatment sites during the GLP safety study.

Performance Data – Clinical

No clinical study was conducted as bench testing was determined sufficient for verification and validation purposes.

Sterilization and Shelf Life

The Broadway 8 Catheter and all device accessories are sterilized with 100% Ethylene Oxide to a sterility assurance level (SAL) of 10^{-6}. The Subject Device and accessories meet the requirements for EO residuals per EN ISO 10993-7 for a limited contact delivery system – externally communicating. The Broadway 8 Catheter and accessories are provided for single use only.

The labeled shelf life for the Broadway 8 Catheter is 1-year. Shelf-life testing (product and packaging) and Distribution Shipping Challenge Conditioning testing were performed on the Subject Device, and the results met established criteria.

Biocompatibility

The Broadway 8 Catheter is categorized as a limited exposure (≤24 hours), externally communicating device with circulating blood contact in accordance with ISO 10993-1 and FDA Guidance, "Use of International ISO 10993-1, "Biological evaluation of medical devices – Part 1: Evaluation of testing within a risk management process." All patient contacting components used in the Broadway 8 Catheter have a history of safe clinical use throughout the medical device industry and/or within Stryker Neurovascular and have supporting biocompatibility data. The results of the biocompatibility testing are summarized in **Table 3** below.

Table 3: Biocompatibility Tests and Results

Test	Test Method Summary	Conclusion
Extract and Direct Hemolysis	ISO 10993-4	Non-hemolytic
Thromboresistance	ISO 10993-4	Non-thrombogenic
SC5b-9 Complement Activation Assay	ISO 10993-4	Non-activator
ASTM Partial Thromboplastin Time	ISO 10993-4	No enhancement or inhibition of coagulation system
Cytotoxicity Study Using the ISO Elution Method	ISO 10993-5	Non-cytotoxic
ISO Maximization Sensitization Study	ISO 10993-10	No evidence of sensitization
ISO Acute Systemic Toxicity Study – Extract	ISO 10993-11	No mortality or evidence of acute systemic toxicity
Material Mediated Pyrogenicity	USP <151>	Non-pyrogenic reactivity
ISO Intracutaneous Reactivity Study – Extract	ISO 10993-23	Non-irritant

Conclusions

The Broadway 8 Catheter is substantially equivalent to the Predicate Device based on similar intended use / indications for use, same or similar materials, same fundamental design, and the same operating principles. The conclusions drawn from risk assessments, the bench testing conducted using the Subject Device compared to the Predicate Device, and an animal safety study demonstrate that the Subject Device is suitable for the indication for use with the associated QJP Product Code. Additionally, the testing results summarized above along with the risk assessment demonstrate that the benefits of the device outweigh any residual risks when used in accordance with device Instructions for Use. Stryker Neurovascular has demonstrated that the Broadway 8 Catheter is substantially equivalent to the legally marketed Predicate Device.