February 11, 2026

Stryker Neurovascular
Natalie Allen
Senior Staff Regulatory Affairs Specialist
47900 Bayside Parkway
Fremont, California 94538

Re: K253032
Trade/Device Name: AXS Lift Intracranial Base Catheter
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous Catheter
Regulatory Class: Class II
Product Code: QJP, DQY
Dated: January 13, 2026
Received: January 13, 2026

Dear Natalie Allen:

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 13484 clause 8.3 (Nonconforming product), and ISO 13485 clause 8.5 (Corrective and 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 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 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,

NAIRA MURADYAN -S

Naira Muradyan, PhD
Assistant Director
DHT5A: Division of Neurosurgical,
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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)*
K253032

Device Name
AXS Lift Intracranial Base Catheter

Indications for Use *(Describe)*
The AXS Lift Intracranial Base Catheter is indicated for the introduction of interventional devices into the peripheral and neurovasculature.

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.

510(k) Summary:	K253032
Submitter:	Stryker Neurovascular 47900 Bayside Parkway Fremont, CA 94538 Facility Registration # 3008853977
Contact:	Natalie Allen
Phone Number:	956-501-5049
Date Prepared:	February 10, 2026
Device Name:	AXS Lift™ Intracranial Base Catheter
Common Name:	Percutaneous Catheter
Classification Name:	Catheter, Percutaneous, Neurovasculature, 21 CFR 870.1250
Product Codes:	QJP, DQY
Device Classification:	Class II
Predicate Device:	AXS Lift™ Intracranial Base Catheter (K243593)
Reference Device:	Benchmark™ Intracranial Access System (K212838)

Device Description

The AXS Lift Intracranial Base Catheter ("AXS Lift") is a single lumen, variable stiffness catheter designed for use in facilitating the insertion and guidance of appropriately sized interventional devices into the peripheral and neurovasculature. The distal catheter shaft has a hydrophilic coating to reduce friction during use. The catheter includes a radiopaque marker on the distal end for angiographic visualization and a luer hub on the proximal end. The distal end of the catheter contains tallow derivatives of bovine origin. It is packaged with one double port rotating hemostasis valve (RHV) and one peel-away introducer sheath. The peel-away introducer sheath is designed to protect the distal tip of the catheter during insertion into the short introducer sheath valve. The AXS Lift Intracranial Base Catheter is compatible with short introducer sheaths with an inner diameter of 7Fr or greater. AXS Lift is supplied sterile, non-pyrogenic, and is intended for single use only.

Accessories

Peel-Away Introducer Sheath

Double Port Rotating Hemostasis Valve (RHV)

Indications for Use

The AXS Lift Intracranial Base Catheter is indicated for the introduction of interventional devices into the peripheral and neurovasculature.

Technological Characteristics and Product Feature Comparison

Stryker Neurovascular has demonstrated that the Subject Device, AXS Lift Intracranial Base Catheter, is substantially equivalent to the Predicate Device (**K243593**) based on the same intended use and principle of operation, same materials and design characteristics. A comparison of the Subject Device and the Predicate Device (**K243593**) is summarized in **Table 1** below.

Table 1: Comparison of Subject, Predicate, and Reference Devices

Device Attribute	Subject Device	Predicate Device	Reference Device
Product Name	AXS Lift™ Intracranial Base Catheter	AXS Lift™ Intracranial Base Catheter	Benchmark Intracranial Access System
510(k) Number	K253032	K243593	K212838
Indications for Use	The AXS Lift Intracranial Base Catheter is indicated for the introduction of interventional devices into the peripheral and neurovasculature.	SAME	The Benchmark Intracranial Access System is indicated for the introduction of interventional devices into the peripheral, coronary, and neuro vasculature.
Product Codes	QJP, DQY	SAME	SAME
Regulation Number	21 CFR 870.1250	SAME	SAME
Classification	Class II	SAME	SAME
Components Supplied	AXS Lift Intracranial Base Catheter, Peel-Away Introducer, Double Port Rotating Hemostasis Valve	SAME	Benchmark Delivery Catheter sold individually or pre-packaged with Penumbra 5F Select Catheter.
Catheter Materials	Commonly used medical grade plastics and metals. Distal end contains tallow derivatives of bovine origin.	SAME	Commonly used medical grade plastics and metals.
Lubricious Coating	Hydrophilic Coating	SAME	SAME
Effective Length	95, 105, 110, 115 cm	SAME	95, 105, 115 cm
Outer Diameter	0.097” (7F)	SAME	0.081-0.083” (6F)
Internal Diameter	0.074”	SAME	0.070” min
Guidewire Compatibility	0.035-0.038”	0.035”	SAME
Radiopaque	Yes	SAME	SAME
Luer Tapered Hub	Yes	SAME	SAME
Tip Shapes	Straight	SAME	Straight, Multi-Purpose
Condition Supplied	Sterile, Single-Use Only	SAME	SAME
Sterilization	Ethylene Oxide (SAL 10^{-6})	SAME	SAME
Shelf Life	36 months	SAME	SAME
Packaging Materials	Tyvek/Nylon Pouch, Polyethylene Support Tube, Packaging Card, SBS Carton	SAME	SAME

Risk Assessment

Risk assessment of the AXS Lift Intracranial Base Catheter has been conducted in accordance with EN ISO 14971 and Stryker Neurovascular risk management procedures. Stryker Neurovascular has determined that the AXS Lift Intracranial Base Catheter raises no new questions of safety or effectiveness.

Non-Clinical Performance Testing

The results of verification and validation testing conducted on the Subject Device demonstrate that it performs as intended and is suitable for its intended use. Specifically, the following tests were performed on the Subject Device to support additional instructions related to use via radial artery access and updated guidewire compatibility:

Table 2: Non-Clinical Performance Testing and Results

Test	Test Method/Applicable Standard	Result/Conclusion
Tensile Strength	Tensile strength measured across full length per EN ISO 10555-1.	Pass
Torque Strength	The distal end of the catheter was constrained while the proximal end of the catheter was rotated in a tortuous model to verify that the catheter can withstand torsional load.	Pass
Kink Resistance	Kink resistance was measured for all junctions of the catheter using progressively smaller radii.	Pass
Burst Pressure	Catheter static burst tested per EN ISO 10555-1.	Pass
Liquid Leak Test	Catheter leak tested per EN ISO 10555-1.	Pass
Coating Integrity	Hydrophilic coating was visually inspected before and after simulated use in a tortuous model.	Pass
Particulate Testing	Particulate was collected from simulated use in a tortuous model, characterized, and compared to the predicate and other comparator devices.	Pass
Simulated Use Test	Simulated use in a bench anatomical model using worst-case interventional devices with radial artery access.	Pass

Biocompatibility

The AXS Lift Intracranial Base 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 Standard ISO 10993-1, "Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process"."* All patient contacting components used in the AXS Lift Intracranial Base Catheter have a history of safe clinical use throughout the medical device industry and/or within Stryker Neurovascular and have supporting biocompatibility data. No additional biocompatibility testing was required in support of this premarket notification which is adding instructions related to use via radial artery access and updating guidewire compatibility.

Performance Data – Animal, Clinical

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

Sterilization and Shelf life

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

The labeled shelf life for the AXS Lift is 3 years. Shelf-life testing (product and packaging) and distribution shipping challenge conditioning testing were performed on the Subject Device, and the results met established criteria.

Conclusions

The Subject Device, AXS Lift Intracranial Base Catheter, is substantially equivalent to the Predicate Device (**K243593**) based on the same intended use, principle of operation, same materials and design characteristics. The conclusions drawn from risk assessment activities demonstrate that the differences do not raise new or different questions of safety or effectiveness. The successful completion of verification and validation testing demonstrates that the device performs as intended.