December 19, 2024

Stryker Neurovascular
Shameena Segui
Senior Staff Regulatory Affairs Specialist
Stryker Neurovascular
47900 Bayside Pkwy
Fremont, California 94538

Re: K241637
Trade/Device Name: Echo™ Intracranial Base Catheter
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous Catheter
Regulatory Class: Class II
Product Code: QJP
Dated: June 6, 2024
Received: November 15, 2024

Dear Shameena Segui:

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,

Michael Mcknight -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)*
K241637

Device Name
Echo™ Intracranial Base Catheter

Indications for Use *(Describe)*
The Echo Intracranial Base Catheter is indicated for the introduction of interventional devices into the 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.

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

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Echo™ Intracranial Base Catheter

510(k) Summary

510(k) Summary

Trade/Proprietary Name:	Echo™ Intracranial Base Catheter
Common Name:	Percutaneous Catheter
Classification Name:	Catheter, Percutaneous, Neurovasculature, 21CFR870.1250 – Class II
Product Code:	QJP
Submitter:	**Stryker Neurovascular** 47900 Bayside Parkway Fremont, CA 94538-6515 (FDA Registration Number: 3008853977)
Contact:	**Shameena Segui**
Date Prepared:	December 18, 2024
Predicate Device:	AXS Infinity LS® Plus Long Sheath (K193034)

Device Description

The Echo Intracranial Base Catheter is a single lumen, flexible, variable stiffness catheter with a 0.100 inch inner diameter, designed for use in facilitating the insertion and guidance of appropriately sized interventional devices into the neurovascular system. It has a radiopaque marker band on the distal end and a luer hub at the proximal end. The distal catheter shaft has a 14 cm lubricious coating to reduce friction during use. It is packaged with a dilator and two rotating hemostatic valves. The Echo Intracranial Base Catheter is compatible with introducer sheaths with an inner diameter of 9F or greater. The Echo Intracranial Base Catheter is supplied sterile, non-pyrogenic, and intended for single use only.

Indications for Use

The Echo Intracranial Base Catheter is indicated for the introduction of interventional devices into the neurovasculature.

Technological Characteristics and Product Feature Comparison

Stryker Neurovascular has demonstrated the Echo Intracranial Base Catheter is substantially equivalent to the Predicate Device, AXS Infinity LS Plus (K193034) based on the same or similar materials, similar design, and the same fundamental operating principles. The Echo Intracranial Base Catheter indication for use is limited to use in the neurovasculature, while the Predicate Device AXS Infinity LS Plus is indicated for use in the peripheral, coronary, and neurovasculature. A comparison of the Subject Device with the Predicate Device is summarized in **Table 1** below.

Table 1: Comparison of Subject and Predicate Device

Detail	Subject Device	Predicate Device
Device Trade Name	Echo™ Intracranial Base Catheter	AXS Infinity LS® Plus Long Sheath
Regulation Number	21 CFR 870.1250	Same
Classification	II	Same
FDA Product Code	QJP	DQY
510(k) Number	K241637	K193034
Intended Use/ Indications for Use	The Echo Intracranial Base Catheter is indicated for the introduction of interventional devices into the neurovasculature.	The AXS Infinity LS Plus is indicated for the introduction of interventional devices into the peripheral, coronary, and neurovasculature.
Materials	Commonly used medical grade plastics & metals.	Same
Coating	Hydrophilic coating	Same
Reinforcement	Stainless Steel Hypotube	Stainless Steel Coil
Outer Diameter	0.118 in.	0.109 in.
Inner Diameter	0.100 in.	0.091 in.
Effective Length(s)	100, 105 cm	70, 80, 90 cm
Sterilization Method	EO Sterilization	Same
How Supplied	Single Use/Sterile	Same
Accessory Devices Provided	2 Hemostasis Valves, 1 Dilator	1 Hemostasis Valves, 1 Dilator

Packaging	Tyvek/Nylon Pouch, Polyethylene Support Tube, Packaging Card, SBS Carton	Same

Risk Assessment

Risk assessment of the Echo Intracranial Base Catheter has been conducted in accordance with EN ISO 14971 and Stryker Neurovascular risk management procedures. Stryker Neurovascular has determined that the Echo Intracranial Base 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.

Performance Data- Bench Testing

The results of verification and validation testing conducted on the Subject Device demonstrate that it performs as designed and is suitable for its intended use. **Table 2** provides a summary of testing performed on the Subject Device:

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
Torque Strength	Measurement of torque strength.	**Pass -** Samples met established acceptance criteria
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 Strength	Burst strength was tested per ISO 10555-1.	**Pass -** Samples met established acceptance criteria
Liner Lamination	Verification of inner liner adherence.	**Pass -** Samples met established acceptance criteria
Tip Stiffness	Measurement of distal tip stiffness.	**Pass –** Device comparable to predicate
Frictional Force	Measurement of coating frictional force.	**Pass** – Device comparable to predicate

Chemical Compatibility	Catheter was measured and visually inspected before and after exposure to various clinically relevant chemicals.	**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 with femoral artery access.	**Pass -** Samples met established acceptance criteria

Performance Data- Animal Safety Testing

A subacute animal study was conducted in compliance with applicable requirements in the Good Laboratory Practice (GLP) regulation (21 CFR Part 58) to evaluate safety of the Echo Intracranial Base Catheter in clinically relevant vessel sizes of healthy swine. Two (2) animals were utilized to complete the study, and in each vessel, three (3) passes were conducted per device. Angiography, necropsy and histopathology of the Echo Intracranial Base Catheter were evaluated and compared to two (2) control devices. The vessels evaluated in the swine model included the renal, lingual, and internal maxillary arteries. Success criteria for all study end points were met. In regard to device safety, vessel injury and tissue response, the subject device performed comparably to both controls, demonstrating vascular safety of the Echo Intracranial Base Catheter.

Biocompatibility

The Echo 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 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 Echo 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. 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 (performed separately)	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	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

Sterilization and Shelf Life

The Echo Intracranial Base 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 EO residuals per EN ISO 10993-7 for a limited contact delivery system – externally communicating. The Echo Intracranial Base Catheter and accessories are provided for single use only.

The labeled shelf life for the Echo Intracranial Base 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.

Conclusion

The Echo Intracranial Base Catheter is substantially equivalent to the Predicate Device (K193034) 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 Echo Intracranial Base Catheter is substantially equivalent to the legally marketed Predicate device.