August 27, 2021

Stryker Neurovascular
Shivani Patel
Senior Staff Regulatory Affairs Specialist
47900 Bayside Parkway
Fremont, California 94538

Re: K202752
Trade/Device Name: AXS Vecta 46 Intermediate Catheter
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous Catheter
Regulatory Class: Class II
Product Code: QJP
Dated: July 23, 2021
Received: July 26, 2021

Dear Shivani Patel:

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 (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 located 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.

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

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

Xiaolin Zheng -S

Xiaolin Zheng, Ph.D.
Director
DHT5A: Division of Neurosurgical,
Neurointerventional
and Neurodiagnostic Devices
OHT5: Office of Neurological
and Physical Medicine Devices
Office of Product Evaluation and Quality
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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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K202752

Device Name
AXS Vecta 46 Intermediate Catheter

Indications for Use *(Describe)*
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 neurovascular system. The AXS Vecta Intermediate Catheter is also indicated for use as a conduit for retrieval devices.

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.

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510(k) Summary
K202752

Introduction:

According to the requirements of 21 CFR 807.92, the following information provides sufficient details to understand the basis for a determination of substantial equivalence.

Submitter Name, Address, and Content:

Submitter: Stryker Neurovascular
47900 Bayside Parkway
Fremont, CA 94538-6515
(FDA Registration Number: 3008853977)

Contact: **Shivani Patel**
Senior Staff Regulatory Affairs Specialist
Phone: 341-465-2199
Email: shivani.patel2@stryker.com

Date Prepared: August 24, 2021

Device Name and Classification:

Trade/Proprietary Name: AXS Vecta® 46 Intermediate Catheter

Common Name: Percutaneous Catheter

Classification Name: Percutaneous Catheter, 21CFR 870.1250 – Class II

Product Code: QJP

Legally Marketed Predicate Devices:

Predicate Devices	Reference Device
AXS Vecta Intermediate Catheter (**K190833**)	Zenith Flex Aspiration System (046 Zenith Flex Catheter) (**K190338**)

Device Description

The AXS Vecta 46 Intermediate Catheter is a single lumen, flexible, variable stiffness catheter. It has a radiopaque marker band on the distal end and a Luer hub at the proximal end. The AXS Vecta 46 Intermediate Catheter shaft has a lubricious hydrophilic coating at the distal end (distal 25cm) to reduce friction during use. It is packaged with one hemostasis valve, and one peel-away introducer.

Indications for Use

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 neurovascular system. The AXS Vecta Intermediate Catheter is also indicated for use as a conduit for retrieval devices.

Technological Characteristics and Product Feature Comparison

Stryker Neurovascular has demonstrated the AXS Vecta® 46 Intermediate Catheter is substantially equivalent to the Predicate device, AXS Vecta Intermediate Catheters (**K190833**) and Reference Device (**K190338**) based on the same or similar materials, same or similar design, and the same fundamental operating principles. A comparison of the Subject device with the Predicate device and Reference device is summarized in **Table 1**: Product Feature Comparison of Subject Device to Predicate Device below.

Table 1: Product Feature Comparison of Subject Device to Predicate and Reference Device

Detail	Submission Subject Device	Predicate Device	Reference Device
Manufacturer	Stryker Neurovascular	Stryker Neurovascular	Stryker Neurovascular
510(k) Number	**K202752**	**K190833**	**K190338**
Device Trade Name	AXS Vecta 46 Intermediate Catheter	AXS Vecta Intermediate Catheter	Zenith Flex Aspiration System (046 Zenith Flex Catheter)
Regulation Number	21 CFR 870.1250	Same	Same
Regulation Name	Percutaneous Catheter	Same	Same
Classification	II	Same	Same
Product Code	QJP	DQY	NRY
Intended Use/Indication for Use	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 neurovascular system. The AXS Vecta Intermediate Catheter is also indicated for use as a conduit for retrieval devices.	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.	The Zenith Flex Aspiration System, including the 046 Zenith Flex Aspiration Catheter, Aspiration Tubing Set, and VC-701 Cliq Aspirator Pump, is indicated in the revascularization of patients with acute ischemic stroke secondary to intracranial large vessel occlusive disease (within the internal carotid, middle cerebral – M1 and M2 segments, basilar, and vertebral arteries) within 8 hours of symptom onset. Patients who are ineligible for intravenous tissue plasminogen activator (IV t-PA) or who failed IV t-PA therapy are candidates for treatment.
Device Description	The AXS Vecta 46 Intermediate Catheter is advanced into the	The AXS Vecta Intermediate Catheter is advanced into the	The InNeuroCo 046 Zenith Flex Catheter is a variable stiffness catheter

	neurovasculature by a physician trained in interventional endovascular procedures using a compatible sheath or guide catheter, and over an appropriately sized microcatheter or guide wire. One peel-away introduce sheath is provided in the package to provide support and facilitate the introduction of the AXS Vecta 46 Intermediate Catheter tip into the sheath/guide catheter valve. Once the assembly is inserted, the peel-away introducer sheath can be removed. Under fluoroscopic guidance, the assembly can be advanced through the vasculature to the desired location.	neurovasculature by a physician trained in interventional endovascular procedures using a compatible sheath or guide catheter, and over an appropriately sized microcatheter, guide wire, and/or the Scout Introducer. Two peel-away introducer sheaths are provided in the package to provide support and facilitate the introduction of the AXS Vecta Intermediate Catheter tip into the sheath/guide catheter valve. Once the assembly is inserted, the peel-away introducer sheath can be removed. Under fluoroscopic guidance, the assembly can be advanced through the vasculature to the desired location.	that has a catheter shaft reinforced with Nitinol to provide support. The proximal section has an embedded nitinol flat wire cross coil that transitions to a nitinol round wire single coil in the distal end. It has a radiopaque Platinum/Iridium marker band on the distal end. The 046 Zenith Flex Catheter is available with an internal diameter of 0.046 inches. The outer diameter is 0.058 inches along the proximal shaft and 0.056 inches at the distal tip. The 046 Zenith Flex Catheter is available in two working lengths: 153 cm, and 160 cm. The 046 Zenith Flex Catheter has a PTFE-lined lumen to reduce friction as it travels over a guidewire. Accessories included with the device are a Tuohy-Borst Hemostasis Valve and peel-away introducer.
Accessory Devices Provided (not in direct contact with patient)	Hemostasis Valve, 1 Peel-Away Introducer	Hemostasis Valve, 2 Peel-Away Introducers, Scout Introducer	Same as Subject device
Outer Jacket	Polymeric catheter	Same	Same
Reinforcement	Nitinol	Stainless Steel/Nitinol	Same as Subject device
Strain Relief	Polyolefin	Same	Same
Inner Layer	PTFE	Same	Same
Catheter Hub	Polycarbonate	Same	Same
Marker Band	Platinum/Iridium	Same	Same
Adhesive	Cyanoacrylate	Same	Same

Outer Jacket Coating	Hydrophilic Coating	Same	Same
Labeled Shaft Outer Diameter	Distal OD: 0.056 in Proximal OD: 0.058in	Distal OD: Vecta 71: 0.082 in. Vecta 74: 0.083 in. Proximal OD: Vecta 71: 0.085 in. Vecta 74: 0.087 in.	Same as Subject device
Effective Lengths	125, 146, 153, 160 cm	115, 125, 132 cm	153, 160 cm
Distal ID	0.046 in.	Vecta 71: 0.071 in. Vecta 74: 0.074 in.	Same as Subject device
Proximal ID	0.046 in.	Vecta 71: 0.071 in. Vecta 74: 0.074 in.	Same as Subject device
Packaging Materials & Configuration	Tyvek/Nylon Pouch, polyethylene support tube, packaging card, SBS carton	Tyvek/Nylon Pouch, polyethylene support tube, packaging card, SBS carton	Same as Subject device
Sterilization Method	EO Sterilization	Same	Same
How Supplied	Single Use/Sterile	Same	Same
Principles of Operation	The AXS Vecta 46 Intermediate Catheter is advanced into the neurovasculature by a physician trained in interventional endovascular procedures using a compatible sheath or guide catheter, and over an appropriately sized microcatheter, or guide wire. One peel-away introducer sheath is provided in the package to provide support and facilitate the introduction of the AXS Vecta 46 Intermediate Catheter tip into the sheath/guide catheter valve. Once the assembly is inserted, the peel-away	The AXS Vecta Intermediate Catheter is advanced into the neurovasculature by a physician trained in interventional endovascular procedures using a compatible sheath or guide catheter, and over an appropriately sized microcatheter, guide wire, and/or the Scout Introducer. Two peel-away introducer sheaths are provided in the package to provide support and facilitate the introduction of the AXS Vecta Intermediate Catheter tip and the Scout Introducer into the sheath/guide catheter valve. Once the assembly is inserted, the	The 046 Zenith Flex Aspiration Catheter is advanced into the neurovasculature by a physician trained in interventional endovascular procedures using a compatible sheath or guide catheter, and over an appropriately sized microcatheter or guide wire. One peel-away introducer sheath is provided in the package to provide support and facilitate the introduction of the The 046 Zenith Flex Aspiration Catheter tip into the sheath/guide catheter valve. Once the assembly is inserted, the peel-away introducer sheath can be removed. Under fluoroscopic guidance, the assembly

	introducer can be removed. Under fluoroscopic guidance, the assembly can be advanced through the vasculature to the desired location.	peel-away introducer can be removed. Under fluoroscopic guidance, the assembly can be advanced through the vasculature to the desired location.	can be advanced through the vasculature to the intended vascular site, with the distal end of the AXS Vecta Aspiration Catheter positioned proximal to the clot. The proximal end of the Aspiration Tubing Set is attached to the "to patient" connection of the canister installed to the VC-701 Cliq Aspirator Pump, and the VC-701 Cliq Aspirator Pump is turned ON. All devices inside of the AXS Vecta Aspiration Catheter are removed. The distal end of the Aspiration Tubing Set is attached to the proximal end of the AXS Vecta Aspiration Catheter. To start aspiration, the switch on the Aspiration Tubing Set is turned ON, and the clot is engaged with the 046 Zenith Flex Aspiration Catheter.

The differences between the devices are not critical as demonstrated above and through the testing referenced below.

Testing Summary

The purpose of this notification is to add functionality to the catheters by adding a new indication for use. All design verification testing which utilized the catheters were reviewed to assess the impact due to the QJP product code. The design of the AXS Vecta 46 Intermediate Catheters and accessories, including device configurations, materials, or dimensions are not changing and therefore had no impact on Design Verification. Therefore, design verification was leveraged from previous AXS Vecta 46 Intermediate Catheter submissions in **K190338**. The impact assessment of the AXS Vecta 46 Intermediate Catheter Verification and Validation activities, including impact to risk management, yielded the following additional Validation study summarized in the section below.

Performance Data – Bench Testing

The results of design validation testing (TP-13700/TR-13700), particulate testing and 3-year aging analysis, (NV00045476 and NV00045788, respectively) conducted on the AXS Vecta 46 Intermediate Catheter demonstrates that it performs as designed, is suitable for the addition of the QJP product code, indication for use, and is substantially equivalent to the legally marketed Predicate devices. Testing was conducted in accordance with ISO 10555-1. The design validation/supplemental confirmatory bench testing is summarized in **Table 2** below.

Table 2. Performance Data - Bench Testing

Test	Test Method Summary	Conclusions
Design Validation Testing		
Simulated Use (Torque, ID, Product Compatibility)	Purpose: to provide objective evidence that test catheter meets applicable user needs: the introduction of interventional devices into the neuro vasculature. Method: Perform a simulated thrombectomy procedure. Track the devices to the target site for endovascular device delivery using a neurovascular in vitro model that replicates the vascular characteristics of human ICA and MCA arteries.	All test samples met the applicable user needs and design specifications.

Test	Test Method Summary	Conclusions
Design Verification Testing		
Burst Testing	Purpose: to measure the maximum static burst pressure of AXS Vecta 46 Intermediate Catheter and to ensure the device can withstand the pressures that may be generated with manual delivery of contrast media after simulated delivery of the most clinically challenging interventional device. Method: Testing was conducted on conditioned AXS Vecta 46 units. The catheter was connected via its hub or proximal end to a pressure generating device. Fluid was applied at a constant rate until product leak or burst while device pressure was monitored.	All test samples met the applicable user needs and acceptance criteria.
Supplemental Confirmatory Particulate Testing		
Particulate Testing	Purpose: The purpose of this test was to document and assess the particulate matter generated from the delivery of neuro-interventional devices through the inner lumen of the AXS Vecta 46 Intermediate Catheter. Method: Particulate testing was conducted with AXS Vecta 46 in a simulated use condition based on the device IFU and a clinically relevant tortuous model.	All test samples met the applicable user needs and acceptance criteria.

Performance Data – Animal Study

The Simulated Use-Animal testing is focused on the safety and efficacy of the device and was performed to support the previously cleared AXS Vecta 46 Intermediate Catheter as part of the system and can be found in **K190338** (cleared as 046 Zenith Flex). Although the addition of the QJP product code will expand the use of the device, the "worst case" use of the device in terms of safety and efficacy is as a Thrombectomy System; therefore, Simulated Use-Animal testing is leveraged to support the QJP product code.

Performance Data – Clinical

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

Shelf Life Testing

The labeled shelf life for the AXS Vecta® 46 Intermediate Catheter is three years. Shelf life testing was performed on the Reference device and the results met the established acceptance criteria. Testing results were reviewed and cleared in **K190338** Zenith Flex Aspiration System (046 Zenith Flex Catheter). Additionally, particulate testing and subsequent analysis between the Predicate and Subject devices confirmed that shelf-life was not impacted by the addition of the QJP product code.

Sterilization

Sterilization testing was performed on the Reference device and the results met the established acceptance criteria. Testing results leveraged from the Reference device were reviewed and cleared in **K190338,** Zenith Flex Aspiration System (046 Zenith Flex Catheter).

The AXS Vecta 46 Intermediate Catheter and all system components are currently sterilized with 100% Ethylene Oxide and provided sterile. A sterility assurance level (SAL) of 10^{-6} has been demonstrated. The AXS Vecta 46 Intermediate Catheter and all system components are for single use only.

Biocompatibility

The AXS Vecta 46 Intermediate Catheter is identical to the catheter component in the Reference device cleared under K190338, Zenith Flex Aspiration System (046 Zenith Flex Catheter). No catheter materials are changing; therefore, biocompatibility is not impacted by the addition of the QJP product code. The completed biocompatibility testing was used to support the biocompatibility of the Subject device.

The AXS Vecta 46 Intermediate Catheter was assessed for biocompatibility in accordance with ISO 10993-1, "*Biological evaluation of Medical Devices – Part 1: Evaluation and Testing within*

a Risk Management Process". The Subject device is considered an externally communicating medical device with circulating blood contact for less than 24 hours.

Conclusion

Stryker Neurovascular has demonstrated the AXS Vecta 46 Intermediate Catheter is substantially equivalent to the Predicate device, AXS Vecta Intermediate Catheter **K190833** based on same intended use / indications for use, same or similar materials, same fundamental design, and the same operating principles. The conclusions drawn from risk assessments and the bench testing conducted using the Subject device demonstrate that the subject device is suitable for the indication for use with the associated QJP Product Code. Additionally, the comparison of the technological characteristics and the intended use of the Subject device and the Predicate device does not raise new questions of safety and effectiveness.

Stryker Neurovascular has demonstrated that the AXS Vecta 46 Intermediate Catheter is substantially equivalent to the legally marketed Predicate device.