December 15, 2019

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

Re: K190833
Device Name: AXS Vecta Intermediate Catheter
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous Catheter
Regulatory Class: Class II
Product Code: DQY
Dated: November 15, 2019
Received: November 18, 2019

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 (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, 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
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K190833

Device Name
AXS Vecta 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 peripheral and neurovascular systems. 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

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: **Shazia Hakim**
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Date Prepared: March 29, 2019

Device Name and Classification:

Trade/Proprietary Name: AXS Vecta® Intermediate Catheter

Common Name: Percutaneous Catheter

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

Product Code: DQY

Legally Marketed Predicate Devices:	**Predicate Devices**	**Reference Device**
	AXS Catalyst 7 Distal Access Catheter (**K183463**)	AXS Vecta Aspiration System (**K172167 & K181354**)

Device Description

The AXS Vecta 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 Intermediate Catheter shaft has a lubricious hydrophilic coating at the distal end (distal 25cm) to reduce friction during use. It is packaged with one Scout Introducer, one hemostasis valve, and two peel-away introducers.

The Scout Introducer may be used in conjunction with the AXS Vecta Intermediate Catheter to facilitate in the introduction of the AXS Vecta Intermediate Catheter into distal vasculature and aid in navigation to distal anatomy. The Scout Introducer has a lubricious hydrophilic coating at the distal end to reduce friction during use. The inner lumen of the AXS Vecta Intermediate Catheter is compatible with the Scout Introducer, guide wires and microcatheters. The inner lumen of the Scout Introducer is compatible with guide wires and microcatheters of an outer diameter of less than 0.044in.

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 peripheral and neurovascular systems. 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® Intermediate Catheter (AXS Vecta® 71 & 74 Intermediate Catheters) is substantially equivalent to the Predicate device, AXS Catalyst Distal Access Catheter (**K183463**) and Reference Device (**K172167 & K181354**) 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**: 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	**K190833**	**K183463**	**K172167 & K181354**
Device Trade Name	**AXS Vecta® Intermediate Catheters (AXS Vecta® 71 & 74 Intermediate Catheters)**	**AXS Catalyst Distal Access Catheter (AXS Catalyst 7 Distal Access Catheter)**	**AXS Vecta Aspiration System**
Regulation Number	21 CFR 870.1250	Same	Same
Regulation Name	Percutaneous Catheter	Same	Same
Classification	II	Same	Same
Product Code	DQY	Same	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 peripheral and neurovascular systems. The AXS Vecta Intermediate Catheter is also indicated for use as a conduit for retrieval devices.	The AXS Catalyst Distal Access 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 Catalyst Distal Access Catheter is also indicated for use as a conduit for retrieval devices.	The AXS Vecta Aspiration Catheter, as part of the AXS Vecta Aspiration System 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

Detail	Submission Subject Device	Predicate Device	Reference Device
			treatment.
Device Description	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 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.	The AXS Catalyst Distal Access Catheter is a sterile, single lumen, variable stiffness catheter designed 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 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 allowing attachments for flushing and aspiration.	The AXS Vecta 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, 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 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 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

Detail	Submission Subject Device	Predicate Device	Reference Device
			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 AXS Vecta Aspiration Catheter.
Accessory Devices Provided (not in direct contact with patient)	Hemostasis Valve, 2 Peel-Away Introducers Scout Introducer	Rotating Hemostasis Valve, Tuohy Borst Valve with Sideport, (2) Peel-Away Introducer Sheaths	Same
Outer Jacket	Polymeric catheter	Same	Same
Reinforcement	Stainless Steel/Nitinol	Nitinol wire and polymer fiber	Same
Strain Relief	Polyolefin	Same	Same
Inner Layer	PTFE	PTFE/Tecoflex	Same
Catheter Hub	Nylon	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: Vecta 71: 0.082 in. Vecta 74: 0.083 in. Proximal OD: Vecta 71: 0.085 in. Vecta 74: 0.087 in.	Distal OD: 6.2F (0.082 in.) Proximal OD: 6.3F (0.0825 in.)	Distal OD: Same Proximal OD: Same
Effective Lengths	115, 125, 132 cm	Same	Same
Distal ID	0.071 in. 0.074 in.	0.068 in.	Same
Proximal ID	0.071 in.	0.068 in.	Same

Detail	Submission Subject Device	Predicate Device	Reference Device
	0.074 in.		
Packaging Materials and Configuration	Tyvek/Nylon Pouch, polyethylene support tube, packaging card, SBS carton	Polyethylene Tube and HDPE Packaging Card	Same
Sterilization Method	EO Sterilization	Same	Same
How Supplied	Single Use/Sterile	Same	Same
Principles of Operation	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 peel-away introducer can be removed. Under fluoroscopic guidance, the assembly can be advanced through the vasculature to the desired location.	The AXS Catalyst Distal Access Catheter is advanced into the neuro vasculature by a physician trained in interventional endovascular procedures using a compatible sheath or guide catheter, and over an appropriately sized guide wire. A peel away sheath is provided in the package to provide support and facilitate the introduction of the AXS Catalyst Catheter tip into the sheath/guide catheter valve. Once the catheter is inserted, the peel away sheath can be removed. Under fluoroscopic guidance, the catheter can be advanced through the vasculature to the desired location. Once the catheter is at the desired location, appropriately sized interventional devices may be inserted into the selected blood vessel.	The AXS Vecta 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, 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 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 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

Detail	Submission Subject Device	Predicate Device	Reference Device
			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 AXS Vecta 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 DQY indication addition. The design of the AXS Vecta Catheters and accessories, including device configurations, materials, or dimensions are not changing and therefore had no impact on Design Verification. Therefore, design verification from previous AXS Vecta Catheter submissions in **K172167** and **K181354** was used to support the subject device with the exception of particulate testing. The impact assessment of the AXS Vecta Catheter Verification and Validation activities, including impact to risk management, yielded the following additional verification testing and Validation study summarized in the section below.

Performance Data – Bench Testing

The results of design verification and design validation testing conducted on the AXS Vecta Catheter demonstrates that it performs as designed, is suitable for the additional indication for use, and is substantially equivalent to the legally marketed Predicate devices. The design verification and design validation bench testing is summarized in **Table 2** below.

Table 2: Performance Data - Bench Testing

Test	Test Method Summary	Conclusions
Design Verification Testing		
Particulate characterization	Purpose: To characterize acute phase particulate generated as a result of product specific simulated use steps. Method: Use light obscuration particle counting to measure the total number of particulates generated during simulated use in each of three size ranges: 10-25µm, 25-50µm, 50-100µm. If >100µm are observed, complete particle count analysis of size ranges ≥200µm, ≥500µm and ≥1000µm.	Particulate generation was acceptable.
Design Validation Testing		
Simulated Use (Torque. ID, Product Compatibility)	Purpose: to provide objective evidence that test catheters meet applicable user needs: the introduction of interventional devices into the peripheral and neuro vasculature. Method: Perform a simulated procedure with delivery of retrieval devices. 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.

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 Aspiration Catheters as part of the system and can be found in **K172167** and **K181354** (cleared as Zenith Flex System). Because the subject AXS Vecta Intermediate Catheter is identical to the catheter component cleared in K172167 and K181354, additional animal testing was not performed for the delivery catheter indication under product code DQY.

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® Intermediate Catheters 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 **K172167 and K181354**.

Sterilization

Sterilization testing was performed on the Reference device and the results met the established acceptance criteria. Testing results were reviewed and cleared in **K172167 and K181354**.

The AXS Vecta Intermediate Catheters are currently sterilized with 100% Ethylene Oxide and provided sterile. A sterility assurance level (SAL) of 10^{-6} has been demonstrated. The AXS Vecta Intermediate Catheters meets EO residuals per EN ISO 10993-7 for a limited contact delivery system – externally communicating. The AXS Vecta Intermediate Catheters are for single use only.

Biocompatibility

The AXS Vecta Intermediate Catheters are identical to the catheter component in the AXS Vecta Aspiration System cleared under **K172167** and **K181354**. No catheter materials are changing; therefore, biocompatibility is not impacted by the addition of the indications for use under the DQY Product Code and the completed biocompatibility testing was used to support the biocompatibility of the subject device.

The AXS Vecta Intermediate Catheters were assessed for biocompatibility in accordance with EN 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 Intermediate Catheters are substantially equivalent to the Predicate device, AXS Catalyst Distal Access Catheter (AXS Catalyst 7 Distal Access Catheter) **K183463,** based on the 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 DQY 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 the device Instructions for Use.

Stryker Neurovascular has demonstrated that the AXS Vecta Intermediate Catheters are as safe, as effective, and perform as well as the legally marketed predicate device.