July 30, 2019

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

Re: K191768
Device Name: AXS Vecta Aspiration System
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous Catheter
Regulatory Class: Class II
Product Code: NRY
Dated: June 28, 2019
Received: July 1, 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,

for Xiaolin Zheng, 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*

K191768

Device Name
AXS Vecta Aspiration System

Indications for Use *(Describe)*

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 treatment.

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

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** Senior Staff Regulatory Affairs Specialist Phone: 510-413-2636 Fax: 510-413-2588 Email: shazia.hakim@stryker.com
Date Prepared:	June 28, 2019
Trade/Proprietary Name:	AXS Vecta® Aspiration System (formerly known as the InNeuroCo Zenith Flex System and InNeuroCo 071 & 074 Zenith Flex Catheters)
Common Name:	Percutaneous Catheter
Classification Name:	Percutaneous Catheter, 21CFR 870.1250 – Class II
Product Code:	NRY

Legally Marketed Predicate Devices

Name of Predicate Device	Name of Manufacturer	510(k) Number
AXS Vecta Aspiration System	Stryker Neurovascular	K190212

Device Description

The Stryker AXS Vecta Aspiration System includes an aspiration catheter and its accessories, including the Scout Introducer, the Peel-Away Introducers, the Hemostasis Valve, the AXS Universal Aspiration Tubing, the Medela Dominant Flex Pump, and the AXS Universal Liner Set.

Indications for Use

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 treatment.

Technological Characteristics and Product Feature Comparison

Stryker Neurovascular has demonstrated the AXS Vecta® Aspiration Catheter (AXS Vecta® 71 & 74 Aspiration Catheters) is substantially equivalent to the Predicate device, AXS Vecta Aspiration System (**K190212**) 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 below.

Table 1. Product Feature Comparison of Subject Device to Predicate Device

Detail	Submission Subject Device	Predicate Device
Manufacturer	Stryker Neurovascular	Stryker Neurovascular
510(k) Number	**K191768**	**K190212**
Device Trade Name	**AXS Vecta® Aspiration System (AXS Vecta® 71 & 74 Aspiration Catheters)**	**AXS Vecta® Aspiration System (AXS Vecta® 71 & 74 Aspiration Catheters)**
Regulation Number	21 CFR 870.1250	Same
Regulation Name	Percutaneous Catheter	Same
Classification	II	Same
Product Code	NRY	Same
Intended Use/Indication for Use	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 treatment.	Same
Device Description	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	Same

	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 AXS Universal Aspiration Tubing is connected to the AXS Universal Liner Set. The AXS Universal Liner Set is connected to the Medela Dominant Flex Pump, and the Medela Dominant Flex Pump is turned ON. All devices inside of the AXS Vecta Aspiration Catheter are removed. The distal end of the AXS Universal Aspiration Tubing is attached to the proximal end of the AXS Vecta Aspiration Catheter. To start aspiration, the aspiration tubing clamp on the AXS Universal Aspiration Tubing is opened, 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	Same
Outer Jacket	Polymeric catheter	Same
Reinforcement	Stainless Steel/Nitinol	Same
Strain Relief	Polyolefin	Same
Inner Layer	PTFE	Same
Catheter Hub	Nylon	Same
Marker Band	Platinum/Iridium	Same
Adhesive	Cyanoacrylate	Same
Outer Jacket Coating	Hydrophilic Coating	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: Same Proximal OD: Same
Effective Lengths	115, 125, 132 cm	Same
Distal ID	0.071 in. 0.074 in.	Same
Proximal ID	0.071 in. 0.074 in.	Same
Packaging Materials and Configuration	Tyvek/Nylon Pouch, polyethylene support tube, packaging card, SBS carton	Same
Sterilization Method	EO Sterilization	Same
How Supplied	Single Use/Sterile	Same
Principles of Operation	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 AXS Universal Aspiration Tubing is	Same

	connected to the AXS Universal Liner Set. The AXS Universal Liner Set is connected to the Medela Dominant Flex Pump, and the Medela Dominant Flex Pump is turned ON. All devices inside of the AXS Vecta Aspiration Catheter are removed. The distal end of the AXS Universal Aspiration Tubing is attached to the proximal end of the AXS Vecta Aspiration Catheter. To start aspiration, the aspiration tubing clamp on the AXS Universal Aspiration Tubing is opened, and the clot is engaged with the AXS Vecta Aspiration Catheter.			
Patient Contacting Components	AXS Vecta Aspiration Catheter and its Accessories		Same	
Pump	Medela Dominant Flex Pump		Same	
Aspiration Tubing	AXS Universal Aspiration Tubing		Same	
Replacement Components	AXS Universal Liner Set		Same	
Aspiration Method	Pump		Same	
Single Use Components	Catheter and its accessories, Aspiration Tubing, Liner Sets		Same	
Reusable Components	Pump		Same	
Maximum Aspiration Pressure	28 in Hg		Same	
Calculated Force at Tip	Catheter ID	Calculated Force at Tip	Catheter ID	Calculated Force at Tip
	0.071 in	0.024 kgf	Same	Same
	0.074 in	0.026 kgf		
Pressure Regulator Method	Adjustable vacuum pressure dial		Same	
Flow Rate	Non-adjustable flow rate		Same	

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

Summary of Non-Clinical Data

Testing was only conducted for specifications that were impacted by the changes to the catheter proximal shaft material (coextrusion), mixed coil winding pattern (cross coil to single) and pitch (.026 to .012) of the stainless steel wire on the proximal section of the catheter shaft of the AXS Vecta 71 and 74 catheters, modification (tightening) of the tip length specification, as well as updating the AXS Vecta 71 marker band tacking to use the same UV adhesive and adhesive curing process as the AXS Vecta 74 cleared in **K181354**. Although an evaluation of the packaging was not required as part of simulated use bench testing, an assessment was included as part of the design validation to confirm that the packaging configuration does not result in any damage to the catheter when opened with the typical sense of urgency; refer to Table 2 below.

Animal Testing

Animal testing previously conducted for the AXS Vecta Aspiration System was leveraged to support the changes to AXS Vecta 71 and 74 Aspiration Catheters. Prior to design changes, Simulated Use-Animal testing was performed to support the previously cleared AXS Vecta Aspiration Catheters as part of the system and can be found in **K190212, K172167** and **K181354** (cleared as Zenith Flex System). Additional testing was not performed because the current design changes do not impact the overall efficacy and safety of the device. The UV adhesive tacking adhesive change does not impact safety or efficacy because the tip design is not changing. The mixed coil and coextrusion changes do not change the distal tip, does not change the outer patient interacting material (Vestamid ML21), and the inner coextrusion material (Pebax 72D) is currently used in the catheter design. The new tip length specification is still within the original tip length specification window and is not anticipated to impact the safety or efficacy.

AXS Vecta Performance Data – Bench Testing

To demonstrate substantial equivalence between the Subject device, AXS Vecta Aspiration System with proposed design changes and the currently cleared AXS Vecta Aspiration System (Predicate device), performance testing was conducted. The tests were performed using standard test methods and pre-determined acceptance criteria and all samples passed. Therefore, this test data supports the argument that the AXS Vecta Aspiration System has similar performance

characteristics as the predicate device. All the testing conducted to demonstrate substantial equivalence are presented in the following table.

Table 2. Performance Testing Summary

Test	Conclusion
Visual Inspection (Packaging: Pouch Visual)	All units met the acceptance criteria and passed Packaging Visual Inspection.
Visual Inspection (Packaging: Undamaged Product)	All units met the acceptance criteria and passed Packaging Visual Inspection.
Tensile Strength	All units met the acceptance criteria and passed Tensile Strength testing.
PTFE Delamination	All units met the acceptance criteria and passed PTFE Delamination testing.
Torque Strength	All samples met acceptance criteria and passed Torque Strength testing.
Catheter Burst	All samples met acceptance criteria and passed Catheter Burst testing.
Leak (Liquid)	All samples met acceptance criteria and passed the Air and Liquid Leakage testing.
Leak (Air)	
Dimensional (ID, OD, & Working Length)	All samples met acceptance criteria and passed Dimensional testing.
Kink Resistance	All samples met acceptance criteria and passed Kink Resistance testing.
Visual Inspection (Transition & Tip)	All samples met acceptance criteria and passed both the transition and tip visual inspections.
Lumen Patency	All samples met acceptance criteria and passed Lumen Patency testing.
Vacuum Drop	All samples met acceptance criteria and passed Vacuum Drop testing.
Tip Flexibility	All samples met acceptance criteria and passed Tip Flexibility testing.
Friction Force	All samples met acceptance criteria and passed Friction Force testing.

Performance Data – Clinical

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

Shelf Life Testing

Shelf life testing previously conducted for the AXS Vecta Aspiration System was leveraged to support the changes to AXS Vecta 71 and 74 Aspiration Catheters and can be found in **K172167** and **K181354**. Shelf life testing was not performed since it was determined that there is no impact on material degradation and the design changes do not impact the overall efficacy and safety of the device.

Sterilization

The subject device is sterilized by 100% EtO and has been adopted into a validated sterilization process in accordance with the principles of AAMI TIR 28:2016 *Product Adoption & Process Equivalence for Ethylene Oxide Sterilization* and per the requirements of ISO 11135:2014 *Sterilization of health-care products – Ethylene oxide – Requirements for the development, validation and routine control of a sterilization process for medical devices.*

Biocompatibility

Biocompatibility testing previously conducted for the AXS Vecta Aspiration System was leveraged to support the changes to AXS Vecta 71 and 74 Aspiration Catheters and can be found in **K172167** and **K181354**. Additionally, though no biological risks were identified, confirmatory tests (cytotoxicity, sensitization and irritation) were conducted to confirm that there is no impact on existing biocompatibility study. Based on the testing results, the AXS Vecta 71 and 74 Aspiration Catheters with the design change is free from biological hazard per ISO 10993-1.

Summary of Substantial Equivalence

The performance characteristics and the test results demonstrate that the AXS Vecta Aspiration System meets the acceptance criteria to determine that the AXS Vecta Aspiration System is substantially equivalent to the predicate device. Furthermore, the intended use, the operating principles, and the design are all equivalent and support the conclusion that all devices are technologically similar. 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 AXS Vecta Aspiration Catheters are as safe, as effective, and perform as well as the legally marketed Predicate device.