April 24, 2019

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

Re: K190212
Trade/Device Name: AXS Vecta Aspiration System
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous Catheter
Regulatory Class: Class II
Product Code: NRY
Dated: March 22, 2019
Received: March 25, 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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Lin Zheng -S
Digitally signed by Xiaolin Zheng -S
Date: 2019.04.24 14:13:14 -04'00'

for Carlos L. Peña, PhD, MS
Director
Division of Neurological
and Physical Medicine Devices
Office of Device Evaluation
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)*
K190212

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 - Ml 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.

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510(k) SUMMARY

Submitter's Name and Address

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Date Prepared

January 31, 2019

Device Trade or Proprietary Name

AXS Vecta Aspiration System

Device Common or Classification Name:

Catheter, Percutaneous, 21 CFR 870.1250, Class II

Product Code:

NRY (Catheter)

Identification of the Legally Marketed Devices to which Equivalence is Being Claimed

Name of Predicate Device	Name of Manufacturer	510(k) Number
Zenith Flex Aspiration System	InNeuroCo, Inc	K181354
Name of Reference Device	**Name of Manufacturer**	**510(k) Number**
AXS Universal Aspiration System	Stryker	K173841

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.

Comparison to Predicate Device

	Predicate Device Stryker AXS Vecta Aspiration System (formerly InNeuroCo Zenith Flex System)	Reference Device Stryker AXS Universal Aspiration System	Subject Device AXS Vecta Aspiration System (with the Medela Dominant Flex Pump)
510(k) Number	K181354	K173841	K190212
Classification	Class II	Class II	Same
Product Code	NRY	NRY	Same
Review Panel	Neurology	Neurology	Same
Indications For Use	The Zenith Flex System, including the Zenith Flex 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.	The AXS Catalyst Distal Access Catheter as part of the AXS Universal Aspiration System is indicated for use in the revascularization of patients with acute ischemic stroke secondary to intracranial large vessel occlusive disease (in 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 are candidates for treatment.	Same

	Predicate Device Stryker AXS Vecta Aspiration System (formerly InNeuroCo Zenith Flex System)		Reference Device Stryker AXS Universal Aspiration System		Subject Device AXS Vecta Aspiration System (with the Medela Dominant Flex Pump)	
Patient Contacting Components	AXS Vecta Aspiration Catheter and its Accessories		AXS Catalyst Distal Access Catheter		Same as AXS Vecta Aspiration System	
Pump	Cliq VC-701 Aspirator		Medela Dominant Flex Pump		Same as AXS Universal Aspiration System	
Aspiration Tubing	Aspiration Tubing Set		AXS Universal Aspiration Tubing		Same as AXS Universal Aspiration System	
Replacement Components	Canister Set		AXS Universal Liner Set		Same as AXS Universal Aspiration System	
Aspiration Method	Pump		Pump		Same	
Single Use Components	Catheter and its accessories, Aspiration Tubing, Canister Sets		Catheter and its accessories, Aspiration Tubing, Liner Set		Same as AXS Universal Aspiration System	
Reusable Components	Pump		Pump		Same	
Maximum Aspiration Pressure	27 in Hg		28 in Hg		Same as AXS Universal Aspiration System	
Calculated Force at Tip	Catheter ID	Calculated Force at tip	Catheter ID	Calculated Force at tip	Catheter ID	Calculated Force at tip
	0.071 in	0.024 kgf	0.060 in	0.018 kgf	0.071 in	0.025 kgf
	0.074 in	0.026 kgf			0.074 in	0.027 kgf
Pressure Regulator Method	Adjustable vacuum pressure dial		Same		Same	
Flow Rate	Non-adjustable Flow Rate		Three Selectable Air Flow Rates: 40, 50, 60 mL		Same as AXS Universal Aspiration System	

Summary of Non-Clinical Data

The subject device has the same materials, packaging, manufacturing process, and sterilization process as the predicate device. Therefore, testing was only conducted for specifications that were affected by changing the pump and the tubing.

Animal Testing

Animal testing previously conducted for the Zenith Flex System was used to support this change. The GLP animal testing performed with the Zenith Flex System included a safety evaluation and an efficacy evaluation at a maximum pressure rating of -27 inHg. However, a calculation of the force at the tip demonstrated that the pressure differences and forces exhibited on the product with the different pumps are minimal. Therefore, this is a modification of an interchangeable component. Since both components have already received clearance for this indication and because the bench top data supports that the catheter still works within the pressure ranges previously established as safe, the animal testing previously conducted can be used to support this change as well.

AXS Vecta Performance Testing

To demonstrate substantial equivalence between the subject AXS Vecta Aspiration System and the predicate Zenith Flex System and the reference Stryker AXS Universal Aspiration System, 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 and the reference device. All the testing conducted to demonstrate substantial equivalence are presented in the following table.

Test	Test Method Summary	Acceptance Criteria	Conclusions
Simulated Use – Bench (AXS Vecta Aspiration System)	AXS Vecta Aspiration System underwent simulated use testing by a physician in a benchtop model	Test samples must meet predetermined user needs	AXS Vecta Aspiration System test samples met the acceptance criteria for Simulated Use - Bench to demonstrate that the AXS Vecta System is substantially equivalent to the predicate device.

Test	Test Method Summary	Acceptance Criteria	Conclusions
Simulated Use Testing – Usability (AXS Vecta Aspiration System)	AXS Vecta Aspiration System underwent simulated use testing by a physician in a benchtop model	Test samples must meet predetermined user needs	AXS Vecta Aspiration System test samples met the acceptance criteria for Simulated Use - Usability to demonstrate that the AXS Vecta Aspiration System is substantially equivalent to the predicate device.
Vacuum Drop / Suction Connector Secure Attachment (Aspiration Tubing Set)	Vacuum pressure measured at source and tip to evaluate pressure difference	Test sample results must meet or exceed existing pressure specifications.	AXS Vecta Aspiration System test samples me the acceptance criteria for Vacuum Drop to demonstrate that the AXS Vecta Aspiration System is substantially equivalent to the predicate device.
Lumen Patency (Aspiration Tubing Set)	Samples were evaluated for lumen collapse during aspiration	Test sample results must meet or exceed existing lumen patency specifications.	AXS Vecta Aspiration System test samples me the acceptance criteria for Lumen Patency to demonstrate that the AXS Vecta Aspiration System is substantially equivalent to the predicate device.

Performance Data – Clinical

No clinical study was conducted as bench and animal testing was determined sufficient for verification and validation purposes. A review was conducted considering published clinical study articles that featured the Reference Device and other devices with similar dimensions used for direct aspiration. The literature review was used to support the proposed indications for use under the NRY product code by using clinical outcomes from devices that are considered technologically similar. This documentation was reviewed within the scope of this change and determined to be applicable.

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.